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GOVERNMENT PATENT POLICY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS

OF THE

COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

EIGHTY-NINTH CONGRESS

FIRST SESSION

PURSUANT TO S. RES. 48

ON

S. 789, S. 1809, S. 1899, and S. 2326

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Dr. WAKERLIN. The American Heart Association deeply appreciates the opportunity you have extended to us to voice our views on the disposition of invention rights in connection with discoveries arising from research activities jointly supported by Government and private funds.

We of the American Heart Association are fully cognizant of the committee's need to arrive at some general patent legislation to protect the public, as represented by the Government's research investment, while also protecting the rights of private organizations. We also realize that such general legislation must be designed to apply to scientific discoveries in such diverse fields as space and defense as well as to scientific discoveries in the field of health in which we have our prime interest.

Nevertheless, in appearing before you we would hope to make you aware of certain technical problems peculiar to medical research which we are sponsoring in the public interest.

Scientific research activities performed in universities and institutions often receive joint and contemporaneous support from commingled funds from two or more sources. Indeed, the U.S. Public Health Service, on many occasions and in the public interest, has encouraged support of research from the private sectors of the economy of this Nation and discouraged exclusive reliance upon Government-financed support. While we heartily agree with this concept, its fulfillment frequently creates a difficult problem. The Public Health Service in its regulations requires that its research grantees agree to transfer to it ownership rights of all inventions. Similarly, the American Heart Association asks its grantees to agree to the assignment of invention rights to it. This at times creates a dilemma for the researcher. And yet only a small fraction of 1 percent of research projects leads to patentable discoveries.

It is no answer that the difficulty may be left to litigation; neither is it a satisfactory solution that the scientists be limited to acceptance of research support from only a single source. It would be infinitely better to provide a method for the equitable disposition of proprietary rights in any discoveries, since the Public Health Service and the American Heart Association both have the benefit of the public as their prime objective.

Assuming that the voluntary health agency has made a substantial investment of public-contributed funds, it should be within the discretion of such agency to achieve fullest public benefit by encouraging all possible development of such discoveries. It follows that there might be instances in which it might be advantageous to the agency and the public to achieve necessary development and application through recourse to financial and specialized manpower resources of a commercial organization. To assure this benefit, it might be necessary to offer the commercial organization leadtime—a reasonable number of years of exclusive license from the date of public introduction of the product—to recoup its developmental investment. The voluntary health agencies believe this to be a practical policy, for the alternative might be to use their own funds to contract commercially for this service on a cost-plus basis. This, in the end, might prove to be considerably more costly to the public.

APPENDIX

Dr. PRICE. No, sir; only under the NIH policy, which I vigorously disagree with. In other agencies they will assign—in fact under a Quartermaster grant, we did develop a very interesting new synthetic plastic, polyxylenol. We are now in interference with a small concern by the name of General Electric as to who is going to get the patent rights on this. They published it a year after we did. But we do not yet know who will get the patent.

But under the Quartermaster, we made an agreement that the Government would have a royalty-free right to use an invention that was made. But we had the right to exploit the private commercial development of this material. The University of Pennsylvania has in fact taken my patent, which I assigned to the University of Pennsylvania, and taken it to a company to see if we can exploit this invention.

Senator BURDICK. Was that developed under Government research?

Dr. PRICE. Yes, sir, under the Quartermaster Corps. I think it is only the NIH where we have no rights residing with the inventor.

No, I like to see the rights reside with the inventor, by all means. This is what I am arguing for. So he can take his invention and bargain with somebody to make use of it.

Senator BURDICK. I am not arguing—I am just pointing out the inconsistency of the company getting it and denying it to the people who do the work.

Dr. PRICE. I think the inconsistency is not there, because I do believe that the whole philosophy of the patent law is that the invention goes to the inventor. He is the one who applies for it and he gets the patent rights.

What he does with it to see that it is made use of differs according to the situation.

In my case, as a professor, I can bargain with it a little bit to see who can make use of it. If I am already working for a company, I have signed an agreement that the inventions I make will automatically be assigned by me to the company in exchange for my salary and other rewards.

Senator BURDICK. Now, you say you are a consultant to Eli Lilly & Co. Suppose that company "A" makes a contract with company "B"—this is purely private—and company "A" has asked "B" to do a research project for them—maybe on a subcontract basis or some other basis. What is the usual practice? Does A or B have the patent rights of any discoveries made there?

Dr. PRICE. Well, I think this is usually a matter of a great deal of concern by the lawyers who write the contract.

Senator BURDICK. I am asking you the practice.

Dr. PRICE. I would think that the practice usually is that the company that provides the money would usually get the rights to develop this.

Senator BURDICK. That has been the testimony before this committee—that A would retain the patent rights.

Dr. PRICE. And if the Government was going to develop and sell the patented inventions, I say the philosophy might be that the Government should have the rights to the patents it finances. But I do not think it will ever develop and sell them under our present economic system.

STATEMENT OF HON. EMILIO Q. DADDARIO, A REPRESENTATIVE IN CONGRESS FROM THE FIRST CONGRESSIONAL DISTRICT OF THE STATE OF CONNECTICUT

Mr. DADDARIO. Mr. Chairman and members of the committee, I am grateful for the opportunity to appear and present my views on this most important subject.

As you, Senator McClellan, have recently been pointing out on the floor of the Senate, anything associated with patents is likely to be a highly complex matter, and a Government-wide patent policy is assuredly so. I wish to compliment this committee for its wisdom in treating the matter accordingly—and not in the simple black-and-white fashion which some people at both ends of this issue tend to advise.

It is not my intent here, today, to recite the history of the Government research patent problem, nor to discuss facts and figures, nor to present you with isolated cases in point designed to prove an argument. You have already been exposed to such discussion, and adequately, I am sure.

But I would like to summarize my philosophy on the Government-owned patent question—a philosophy which I believe is shared by many of our colleagues. It is also a philosophy which has emerged from a good deal of interest and time spent in study and hearings.

As you may know, I have chaired a special subcommittee which was charged with the duty of reviewing the Government patent relationship in connection with our national space program. We spent better than 4 years on the subject between 1959 and 1964; we issued three major reports, reported out two bills amending the National Aeronautics and Space Act patent section and passed one of them through the House. So, while I am not a patent lawyer and make no pretense of being an expert in regard to the patent system itself, I am familiar with the issues surrounding Government patent policy.

Mr. Chairman, I have three main basic convictions which I should like to submit to you and your committee on this matter.

First—it is very clear to me that where federally financed research and development is concerned both the Government and contractor have logical and justifiable equities in the ownership of such patents as may arise in the course of the contract.

It is idle to pretend that the Government, at least in its role of representing the public, has no reason for nor interest in the title to such patents. Without the use of the taxpayers' funds the patent might not evolve in the first place—and the fact that the United States always has a free and irrevocable license to use the patent item or to have it produced by any party it chooses for governmental purposes is not always sufficient to protect the public interest. By the same token, it is equally unrealistic to assert that the contractor, who may have contributed as much or more than the Government in terms of know-how and the expenditure of its own money toward the development of the patent, has no claim to ownership nor the exclusive right to utilize the patent for commercial purposes. To take the latter position may be unfair to the large contractor and, in addition, downright disastrous to the small contractor, to whom a patent portfolio is an important

tion that is carried out in the Du Pont Co., in the General Electric Co., in Hercules Power, in Lilly, and so on, that is available because of the patent laws.

So one is this disclosure of scientific information. And this is a great satisfaction, incidentally, for the scientists. We like to see what we have done, see the light of day. And I can assure you that the publication of the work as a patent or as a paper which is made possible by the patent law is a public benefit, but also a private satisfaction to the inventor.

Second, the other public benefit is this business which I have emphasized so much, the incentive to get the investment into development—take the bare invention and make it into a product. And I think these are the public benefits that are important, and it is the vast investment of Government funds in research and development that now make this a very important public policy decision, as to how the use should be made of these patent rights.

Senator BURDICK. If the Government retains the patents, there is a wide-open field for the public to develop that patent; is there not?

Dr. PRICE. If the Government owned the patent?

Senator BURDICK. Yes. Everybody has a right to it.

Dr. PRICE. Everybody has the right to it, but nobody has any incentive to invest in its development if it is not obvious that this is a major breakthrough. There will certainly be some patents, I agree—there will be some patents like, we could say, the cure for the common cold. If you could find a way to cure this, every drug company would make it, and every drug company would want to have it in its line of products, and if it was available as a Government patent, they would do it whether it was exclusive or not.

But for many, many products this is just simply not the case. It is not obvious that this is going to be better until it is out and tried.

Senator BURDICK. Well, certainly the public will have a better opportunity to develop a patent if they know about it than if they do not know about it and cannot develop it, if it is controlled by somebody.

Dr. PRICE. Everybody knows about a patent the minute it is published.

Senator BURDICK. They do not have the right to develop it.

Dr. PRICE. They do not have the right to utilize it unless they get a license to do so.

Senator BURDICK. I must respectfully disagree with you, sir. I think if the patent is available to the public, the development possibilities are greater than if they are hemmed in some way.

Dr. PRICE. I think the concern I have is that the public will not and cannot spend $5 million or $10 million to take the invention and make a product out of it.

Senator BURDICK. Some smart entrepreneur will do it, a businessman.

Dr. PRICE. But he will have to prove it with a $10 million investment. If somebody else can then come in after it is proven, and after he has developed it, and make it for a fraction of that, it does not make sense to me.

Senator BURDICK. Just a moment. There is $5 billion to $15 billion involved here. The taxpayers of the United States have some money

many "in between" cases, it would be possible to work out an equitable arrangement of exclusive licensing or whatever degree thereof appeared appropriate.

I should like to emphasize that the executive agencies which must deal with the patent problem on a day-to-day basis, without exception, have learned the importance of the kind of flexibility which S. 1809 would provide. Even those agencies which have been required or most prone to exert title in the Government, such as the Atomic Energy Commission, the National Aeronautics and Space Administration, and the Department of Health, Education, and Welfare, have found it necessary to alter their practice according to the individual circumstances. You have heard much about the desirability of the practices of the AEC policy from those who favor a rigid Government-ownership position. Yet, if you look at the 1964 annual report of the AEC for the Joint Committee, you will find considerable variation in patent treatment. AEC now holds about 3,000 patents. On these it has granted nonexclusive licenses to over 1,000 private firms; 561 have been retained by contractors; 330 exclusive licenses have been granted in "outfield" cases; and title to 400 patents has gone to contractors, subject only to a Government license.

Certainly this, it would appear to me, is persuasive evidence of the need for flexibility in whatever system is adopted.

I should like now to turn to several somewhat more specialized aspects of the patent policy problem.

One of these is the international phase, which has not been widely discussed. We have heard much about "giveaways." But a most vulnerable "giveaway" condition occurs in regard to foreign rights when our Government takes title to inventions.

Let me explain. According to U.S. patent law, an application for patent must be applied for by the inventor himself. The Philippine Republic is the only other country in which this is required. In countries such as England, France, or Germany, or many of the Latin American countries, a patent may be obtained by a person who brings the invention into that country even though he imported it from another country such as the United States.

Thus, when inventions are freely available to the public in the United States, we are powerless to stop people in other countries from obtaining patents in other countries of the world on the basis of inventions made in the United States by American inventors. When this happens our own Government cannot use the inventions on which the patents are obtained, and even the American contractors or inventors who were responsible for making the inventions cannot practice them in those countries without infringement or obtaining a license. And this at a time when our balance-of-payments situation is critical and of immense economic importance.

Another aspect of the problem concerns the so-called advance waiver. You may and probably have been told that there is no excuse for waiving title on an invention not yet in being. In the main, I tend to agree with this position. And yet there are situations where it is most beneficial to the Government to be able to waive in advance. I refer to cases where a Federal agency, having discovered that some potential contractor has already done considerable private research in an area vital to the interests of the Government, approaches that con-

Senator McClellan. The difference I am interested in here is where the Government goes out for the specific purpose and provides research funds in order to develop drugs that are beneficial to health. Very well. The Government finances research to develop a better airplane or something like that, and in the course of that it gets the product it wants, but there is a byproduct or a fallout product of a discovery or an invention—and in those instances I think the Government could very well let private enterprise have it, take it, and develop it and get it on the market if it has a civilian use or a general consumer use.

But when the Government specifically finances the experimentation and the development of drugs to effectuate a cure of disease, I think there is a little difference—it comes in a little different category.

Dr. Price. Well, the Government finances research, which leads to the discovery of a better cure of some disease, and this is the invention. Now, somebody wants to buy this thing from a drugstore shelf. The question is, How do we go from the discovery to the product which you and I can buy on the drugstore shelf?

Now, in many cases, in drugs as well as in the new rubber or a new plastic—or any other product, there is a question whether this drug will prove to be better, and there is a vast investment necessary—I am a consultant for the Eli Lilly Co., and I see the immense expenditures it takes to take a new drug that you have discovered that shows some beneficial possibilities in animal tests, to find out whether that drug is going to be useful in human beings—this again requires a vast investment. And it seems to me that you need to provide an incentive for that investment just as you need to provide an incentive for the investment to develop other new products for the public.

Now, I think the Government has a very great responsibility to regulate the use of drugs. But I think that there is need, and I think it is important to consider this—I can be wrong, of course, Senator—but you asked my opinion. In my opinion as a chemist, there is just as much need for an incentive to develop a new drug as there is incentive to develop a new rubber.

Senator McClellan. I do not know any of us who could not be wrong. Very well.

Senator Burdick.

Senator Burdick. One of the things that puzzles me about your testimony is that you speak of incentives. Yet the Talon fastener that you refer to, most anything else, comes out of the human mind—that is where it comes from. You are perfectly willing to deny to a man who has spent a lifetime in science any patent rights at all for the work that he accomplishes for working on a Government contract, are you not?

Dr. Price. I am afraid that I do not understand.

Senator Burdick. All right. Company A hires a scientist who has been working in your university for all his life. He is put on a project X. There he makes a discovery. That man gets no patents rights for his work. He is the one that should be stimulated—he is the one that should have the incentives. Is that correct?

Dr. Price. I understand. Yes. I think what you are saying is that when a man goes to work for a company he no longer privately

Senator McCLELLAN. I have tried to say repeatedly that I have no unyielding conviction with respect to the issues involved in this legislation. I think that the Government's rights and the taxpayers' rights should be amply protected, but there is one aspect that is quite persuasive, may be conclusively so with me and, that is, that the Government goes out to a company that has built up a wide experience in a given field, has mobilized the know-how, has it in place and ready, and the Government says, "in this particular area we would like to have a given thing—we will help finance it—we will finance it, we will give you a contract to go right to it and put on a crash program and get this thing done for us."

Now that same company might very well prefer to use its research, its skill and know-how for application to something of its own or to continue on with what it is doing, and thus reap the full benefit from that effort. But there are those who are contending, apparently, that if the company enters into a contract with the Government allowing it to take full advantage of all of that which has been done to bring the research in that area up to its present state so that it becomes the foundation for the new research, and if the Government puts in a dollar or anything then it ought to have all of the patent rights that ensue therefrom. I do not think that is equitable. And that is the thing that gives me concern. Where the Government provides all the funds and starts some new experience and does not get the advantage of something that has already been accumulated there may be some justification for pursuing the patent rights, there may be some justification for stating that the patent rights should go only to the Government, and that the Government should take it and make it available to anyone who wants to use it. I have simply tried to get the best evidence and information that we can to help us establish the equity as nearly as it can be done between Government and private enterprise in this field, to establish adequate protection for the taxpayers, and as the politicians often say, to protect their tax money—to protect their interests—and at the same time to be fair and to be just to those who made investments on their own and have taken the risk in the private enterprise field and have developed to a point where it becomes a great asset, the framework, so to speak, for the goals that the Government seeks and needs.

And if someone has said that this is simple, I do not believe that they know very much about the problem, because it is not simple, it is not easy to find the proper solution to this. I think you have made a very fine contribution to the record of this committee which we will have to carefully study. I, personally, appreciate your presence and the time that you have given us.

Mr. DADDARIO. Thank you, Mr. Chairman, for those remarks.

I would like you to know that with some slight modifications it is my intention in the near future to submit a bill quite comparable to S. 1809 in the House.

Senator McCLELLAN. I am sure that S. 1809 may need some revisions and it may well form the basis for the legislation that this committee will report, and it may not. I do not know, but, in any case, it was the best that I could find at the time of introduction. I think that this is a matter of some urgency. There is no disposition on the part of this committee as I indicated in my opening statement to try to expedite this legislation without giving it the attention and the study

Dr. PRICE. You cannot get along without it now, Senator. But it took 10 years to convince people——

Senator MCCLELLAN. What type of a terrible time did he have?

Dr. PRICE. It took a long time to convince people that this was not a dangerous weapon but a useful invention. And literally this man had a terrible time to convince people.

Senator MCCLELLAN. That is a very vivid and convincing illustration in my mind.

Dr. PRICE. But this happens for all kinds of discoveries—it is a very rare scientific discovery that is made for which everybody says "Ah, this is just what we were waiting for." For example, many kinds of rubber were available in 1949 so it took lots of convincing that our rubber was going to turn out to be a much better product.

Senator MCCLELLAN. That is one illustration. Can you give another?

Dr. PRICE. Well, I think my chloroquin antimalarial drug is another illustration on the negative side. I am firmly convinced that the process we had developed, which was, in this case, actually taken through a development stage at Government expense, was clearly more efficient and more economical as a procedure for making this compound than the existing one. Yet it was not reduced to practice. The money to invest in a plant——

Senator MCCLELLAN. Would you hold your answer a minute? I have somebody on the telephone I must speak to.

I am sorry. Go right ahead.

Dr. PRICE. As to this rigidity of the Long bill, it seems to us there are very great differences in how an invention might be made useful to the public. There are some—for example, if you have the cure for the common cold—that everybody will want to buy it immediately. But there are many other inventions which prove to be extremely useful, but which when first discovered are not obviously useful, and it takes a lot of faith, a lot of conviction, and a lot of investment of effort before it can be proven that these inventions will be useful to the people. And we believe there ought to be some flexibility to provide these incentives in a variety of different situations.

We think that the Long bill is a little too rigid in not providing enough incentive for some of these situations.

Senator MCCLELLAN. Now, one other question.

You may have already answered this. The answer you have just given may have covered this.

You said on page 5:

> As is evident from the foregoing, the American Chemical Society believes that there are two major public benefits stemming from patents.

Then, No. 2:

> Providing incentive for the frequently massive investment necessary to convert an invention into a product available to the public.

And you say:

> The second of these proposals would be seriously undermined and controverted by the basic philosophy inherent in S. 1899.

Did your previous answer cover that?

Dr. PRICE. I think, essentially——

Senator MCCLELLAN. Did not your previous answer cover that?

S. 789, S. 1809, and S. 1899 each deals with the acquisition, disposition, and use of inventions and data resulting from contracts directly concerned with research and development financed at taxpayer expense. None of them reaches the situation where negotiated contracts result in substantial public support of the independent research programs of contractors through the assumption of such research costs in overhead rates. Under current administrative policies, the Government does not, so far as we know, obtain any rights with respect to inventions and data financed at taxpayer expense in this manner. We are not in position to make any recommendation concerning the proper policy to be followed. But the question of indirectly Government financed research and development is closely connected with the subject covered by the three bills, and we believe there is sufficient at stake in the way of Government funds involved and inventions made to warrant bringing the matter to your attention.

(Mr. Welch then testified with respect to S. 1047 which is being printed separately.)

Senator BURDICK. Getting back to another portion of your testimony, you referred to S. 789, S. 1809, and S. 1899, and you state, "none of them reaches the situation where negotiated contracts result in substantial public support of the independent research programs of contractors through the assumption of such research costs in overhead rates. Under current administrative policy, the Government does not, so far as we know, obtain any rights with respect to inventions and data financed at taxpayer expense in this manner."

Can you give me an example of that type of situation?

Mr. WELCH. Could I have Mr. Rubin answer that question? He is with our audit group.

Senator BURDICK. Yes.

Mr. RUBIN. The situation described here is a situation where a contractor has a so-called independent research and development program. The Government will negotiate with a contractor in advance as to the extent of the program which the Government will be willing to participate in through inclusion in the contractor's overhead as an allowable item of cost. This cost is then allocated to the contracts then in process which may involve production or research and development. The Government participation may cover as much as 80 or 90 percent of the contractor's costs.

The extent of the independent research programs is rather significant in many cases. We have received an estimate made within the Department of Defense that indicates that the amount of the total of such programs, I think about a year or two ago, was in the neighborhood of $900 million annually. That is a rather significant figure.

Senator BURDICK. I do not quite understand it yet. The Government pays a consideration to the contractor to do this work.

Mr. RUBIN. The Government, you say, pays a consideration?

Senator BURDICK. Yes.

Mr. RUBIN. The Government will pay for a share of it; yes.

Senator BURDICK. What is the difference between a regular and a development contract?

Mr. RUBIN. The point that we make here is that the way these bills read they relate only to contracts directly concerned with research and development. These contracts will not specifically provide for

would not necessarily obviously become the property of the Government since the scientists and engineers doing the work must have used some of the know-how they had built up though their experience. Some consideration must be given to the employer who has been supporting and developing an efficient staff through the years before taking on the Government-supported project. In such cases it seems appropriate for each Federal agency to negotiate the best arrangement for all concerned as has been the practice in the recent past under the Kennedy patent policy of October 1963.

There are great differences in financing research leading to inventions. This might be represented at one extreme by the almost total Government support of, say, a large electrical company's missile and space laboratory, and at the other extreme by a small grant to help a university or foundation research program. This raises the question of the difference in the mode of utilization of any consequent discoveries. Only the Government will purchase the results of research on the better space vehicle for the foreseeable future. But if my research on polymers, supported in part by Federal funds, produces a better foam rubber or a better insulating plastic, this will be bought largely by private citizens from commercial firms, and then only if they are convinced of its merit over existing products. But in order to find out whether my better foam rubber will be practical and will be accepted by the public may require investment of many years and millions of dollars. Some incentive for this large investment is necessary, one of the important reasons, the society believes, for the constitutional rights granted to patentees. It is important to emphasize that a profit is made on the investment of research and development funds only if the public finds the product useful and buys it. For example, I have been told that during the past decade a major company invested $10 million in a new product only to have a competitor produce a superior one, thereby making this expenditure virtually worthless.

COMMENTS ON THE PENDING LEGISLATION

As is evident from the foregoing, the American Chemical Society believes that there are two major public benefits stemming from patents: (1) The stimulation of disclosure of new scientific and technical information; and (2) providing incentive for the frequently massive investment necessary to convert an invention into a product available to the public.

The second of these purposes would be seriously undermined and controverted by the basic philosophy inherent in S. 1899 (Long bill).

Furthermore, we believe that section 4(a)2 of S. 1809 (McClellan), in fact, would serve the same undesirable purpose for the area of "public health, welfare, and safety" and therefore urge deletion of this principle. If incentive for investment necessary to make inventions available to the public is necessary in other areas, it should certainly be available to stimulate development in such vital areas as health, welfare, and safety.

The society also would like to comment on section 6 of Senator Saltonstall's bill, S. 789. This section states that the contractor's rights in an invention under section 3(e) may be voided by the Government if, inter alia, the invention is not, or is not about to be, placed in commercial use. While provision is made for obtaining an extension of time, the 3 years allowed is considerably short of the interval commonly required for the development of chemical processes and products. The general principle evident in this portion of S. 789 seems reasonable to the society, but it believes that significantly more time should be allowed the contractor in which to evaluate fully the commercial potential of an invention. As a guide, an interval of 5 to 7 years is not unreasonable in such situations.

In summary, the society vigorously opposes the basic principle of S. 1899 and supports the basic approach taken by S. 789 and S. 1809.

We thank you for the opportunity to present our views, and assure you of the society's willingness to cooperate with the committee as it continues to investigate the vital topic of Federal patent policy.

Senator McCLELLAN. Just two questions.

On page 4 of your written statement you say:

We feel that the rigidity called for by S. 1899 would not result in the greatest usefulness and benefit to the general public.

Why?

have been debated so vigorously, so thoroughly, and for such a long time. The several hearings your subcommittee has conducted on this point have made you thoroughly acquainted with the opposing viewpoints. The Department of Defense presented its views to your committee in 1961, and we reaffirm those views today.

Suffice it to say that the mainspring of the patent policy which the Department of Defense has followed has been incentive. In contracting for national defense research and development the Department of Defense has sought, among other things, to take advantage of the incentives implicit in the patent system. The patent system was established to encourage invention, disclosure, and exploitation of new ideas. It is a fundamental part of the economic framework of incentives in which American industry operates.

When the Department has agreed that contractors and their subcontractors may retain patent rights in inventions they make in performing research and development under Defense contracts, provided the Government obtains complete rights to use the inventions itself or to have them used by others in work for the Government, the Department has hoped to maximize the incentive to both large and small companies to seek out and compete for Defense work, to bring their best privately developed background and most promising ideas and most talented people to the task, and to report freely and readily the full results of their work, without fear of losing exclusive commercial rights in their ideas, which would normally be theirs.

The Department has acquired what it bargained for. To accomplish its purposes the Department has not generally needed full title to its contractors' inventions, and it has believed that requiring full title would undesirably dilute a necessary incentive for Defense work. At the same time, it has considered that when the invention remains in private hands, the incentives of the patent system are available to protect and encourage private investment in bringing inventions made in Defense work to the commercial market and thus making them available to the general public.

However, the Department of Defense has long recognized that its general policy of seeking only a governmental license to use its contractors' and subcontractors' inventions is not necessarily the only appropriate policy for the entire Government. Other Government agencies have different missions and roles to play in the national economy, and these different missions and roles may require a different patent policy. In other words, in these instances there may be a specific governmental purpose to be served in taking title. For example, while the Department of Defense does not contract to develop inventions for commercial use—and inventions found useful for military purposes often require considerable private investment to make them commercially useful—other Government agencies do have a mission of developing inventions to the point of commercial application and making them available to an industry without the need for further development. The research and development in commercial fertilizers carried on by the Tennessee Valley Authority is an example of this kind of agency mission.

In 1961, following prolonged congressional interest in the patent policy question, the Department of Defense formally recognized in

if, inter alia, the invention is not, or is not about to be, placed in commercial use.

We agree that there should be a provision to make certain that inventions are used, if they are useful to the public. While provision is made for obtaining an extension of time, the 3 years allowed is considerably short of the interval commonly required for the development of chemical processes and products.

So, as I say, while this general principle seems reasonable, we believe that significantly more time should be allowed the contractor to evaluate fully the commercial potential of an invention and something of the order of 5 to 7 years would seem reasonable to us, rather than the 3 years provided in Senator Saltonstall's bill.

In summary, the society vigorously opposes the basic principle of S. 1899 and supports the basic approach taken by S. 789 and S. 1809, on these very important matters of Government patent policy.

We express our appreciation for the opportunity to present our views. If there is anything we can do further to assist the committee in its investigation, we would be delighted to do so.

Thank you very much.

(The full statement of Dr. Price follows:)

STATEMENT BY THE AMERICAN CHEMICAL SOCIETY

Mr. Chairman, distinguished members of the subcommittee, my name is Charles C. Price. I am the chairman of the department of chemistry at the University of Pennsylvania in Philadelphia, Pa., and president of the American Chemical Society. I appear before you today in the latter capacity. The society is an organization founded in 1876. It is the largest membership organization devoted to a single science in the entire world. Its annual budget exceeds $17 million. Incidentally and importantly, it should be noted that the society was chartered by the Congress of the United States under Public Law 358, 75th Congress, chapter 762, 1st session, and signed into law by President Roosevelt on August 25, 1937.

Our interest in presenting the views of the society on legislation to establish a Federal patent policy is based primarily on our charter, paragraph 2 of which states as follows:

"SEC. 2. That the objects of the incorporation shall be to encourage in the broadest and most liberal manner the advancement of chemistry in all its branches; the promotion of research in chemical science and industry; the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education, and attainments; the increase and diffusion of chemical knowledge; and by its meetings, professional contacts, reports, papers, discussions, and publications, to promote scientific interests and inquiry, thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

GENERAL OBJECTIVES

The general objectives of everyone participating in these hearings are undoubtedly similar whether they are speaking for themselves or representing large organizations. Everyone wants the United States to utilize its discoveries for the greatest benefit of its people. But, there are honest differences of opinion as to the best way to accomplish this general objective. The society has reviewed the proposed legislation and will have some comments to make on each bill under consideration; namely, S. 1809 by Senator McClellan, S. 1899 by Senator Long, and S. 789 by Senator Saltonstall. We find the first two of these generally acceptable, but not that introduced by Mr. Long.

emerge from the contract work. The safeguards which I mentioned include the right to require the contractor to make the invention available to others for use or manufacture to the extent the invention is required for public use under a governmental regulation or to the extent it is necessary to fulfill health needs, and also the right to require the contractor to grant licenses to others if he refuses to commercialize his invention or permit others to do so on reasonable terms within a reasonable time.

The President's statement strikes a proper balance between complete public ownership or complete private ownership of inventions and applicable patent rights which result from performance of research and development work financed by the Government. In addition—and I emphasize this—it provides the administrative flexibility which is essential if the various agencies of the Government are to execute their primary missions and at the same time achieve a consistency in patent policy in areas of endeavor common to several agencies.

The Department of Defense patent policy fully implements President Kennedy's statement of patent policy. It is interesting to note what has happened in terms of division of patent rights. Operating under the old Defense policy, 17 research and development contracts in fiscal year 1963 contained a clause acquiring title to the patents for the Government. In fiscal year 1964 the number of such contracts increased to 29, making a total of 46 such contracts in fiscal years 1963 and 1964. The remainder, more than 99 percent, contained the license clause. In contrast, under the ASPR implementation of the President's statement, for the month of April 1965 alone, out of 695 research and development contracts awarded, 68 contained the title clause, 505 the license clause, and 119 a clause which defers the allocation of rights of inventions until disclosure, and 3 did not contain patent clauses (because the subject matter made it unnecessary to do so). In our opinion, these figures demonstrate the marked swing from what was substantially a hundred percent license policy to the more balanced result which was intended by the President's statement.

Nevertheless, we are well aware of the need to improve the implementation of this policy by our contracting officers. They have decisions to make which they have never had to make before. These decisions are not easy. We have several thousand contracting officers located all over the United States, and we are continuing our efforts to impart to each one a common understanding of the Department of Defense implementation of the President's policy. In addition we believe that further revision of the regulations to assure clarity and consistency is necessary, and we expect that changes will be made as a result of analysis of our operating experience.

However, we have enough experience to form the firm opinion that President Kennedy's statement of patent policy is the soundest formulation of policy ever achieved in this most difficult field.

The Department of Defense therefore supports legislation which incorporates the patent policy stated by the President. Because, Mr. Chairman, your bill S. 1809 in large part does this, the Department of Defense supports it.

To illustrate the need for flexibility and the need to consider cases separately, one need only think of the wide variety of situations which can and do exist. For instance, if Federal money is used to build a completely new staff which will work on a Government-sponsored project, the rights to patentable discoveries obviously should probably reside with the Government. On the other hand, if such funds are directed toward a project whose personnel each had averaged 10 years of experience with the firm contracted to do the job, patentable results would not necessarily obviously become the property of the Government since the scientists and engineers doing the work must have used some of the know-how they had built up through their experience. Some consideration must be given to the employer who has been supporting and developing an efficient staff through the years before taking on the Government-supported project. In such cases it seems appropriate for each Federal agency to negotiate the best arrangement for all concerned as has been the practice in the recent past under the Kennedy patent policy of October 1963.

There are great differences in financing research leading to inventions. This might be represented at one extreme by the almost total Government support of, say, a large electrical company's missile and space laboratory, and at the other extreme, by a small grant to help a university or foundation research program. This raises the question of the difference in the mode of utilization of any consequent discoveries. Only the Government will purchase the results of research on the better space vehicle for the foreseeable future. But if my research on polymers, supported in part by Federal funds, produces a better foam rubber, or a better insulating plastic, this will be bought largely by private citizens from commercial firms, and then only if they are convinced of its merit over existing products. But in order to find out whether my better foam rubber will be practical and will be accepted by the public may require investment of many years and millions of dollars.

I can cite one example in history—the Talon fastener, which took many, many years of vigorous effort before the public was convinced that they needed a zipper in place of buttons.

In my own personal research during the war, my group developed a new procedure for the synthesis of the antimalarial drug, chloroquin, which I think remains today the best and most widely used drug for the treatment of malaria. Our synthesis was far more efficient and superior to the German synthesis. And through some Government contract funds, one company did some development work on trying to develop this procedure for making this drug. But under the terms of the program, the Government owned the patent and the patent would be dedicated to the public. The ultimate decision by this company was that they could not afford under these circumstances to risk several million dollars to build a plant, to prove that this was a better process, if anyone else could then step in and utilize the process. So for 20 years we have paid more for chloroquin because the old, inefficient German process is still used for its production.

In the case of my research on polypropylene-oxide rubber, this was done on university programs where the patent rights could be assigned to a company, and in this case the company did invest a great deal of

statement, in the deferred situation, a contractor (normally a company without a commercial background) can usually expect to obtain title if it can show a positive plan for commercializing the invention. However, the burden is on the contractor to show the plan, and on the Government to decide whether fundamental public policy requires that title vest in the Government. In particular, this kind of decision should not be subject to judicial review. Judicial review may be appropriate to procedures which have as their purpose divesting rights previously established. However, here the issue is the allocation of rights in the first instance, a procedure substantially different from divestiture.

In general, however, we would favor enactment of S. 1809, if changed in accordance with our recommendations. We believe that this bill can be interpreted to preserve the administrative flexibility which is contained in the President's policy.

With respect to the other bills before the subcommittee dealing with Government patent policy, the Department of Defense considers that S. 789 contains desirable features but falls short of certain important provisions of the President's statement and therefore the Department does not recommend its enactment. For example, S. 789 would limit the exercise of "march-in" rights to cases in which the Government might have acquired title at the time of contracting but did not. This is more restrictive than the President's statement. We believe that "march-in" rights should be available in any case in which the Government has obtained only a license.

The Department of Defense strongly opposes enactment of S. 1899. This bill would be in effect require the Government to take title to all inventions and applicable patents emerging from federally financed research and development. Such a policy would have, in our judgment, severly adverse long-range effects on the Defense research and development program. It would tend to concentrate our work in only those firms which take our contracts on any terms they can get them and to cut defense work off from the best research work carried on by U.S. companies for their own commercial purposes. It would discourage inventive small business from working for the Government. It would remove the patent incentive and protection for commercializing many inventions made for the Government.

While S. 1899 would provide for after-the-fact review of each invention—an exceedingly cumbersome administrative process—the requirements which would have to be met before a contractor could obtain title to his invention are such that in practical terms no patents would be acquired by contractors.

Our detailed comments on these bills have been provided in written form to the chairman of the Judiciary Committee.

Mr. Chairman, this concludes my statement. I am ready to answer any questions you may have.

Senator McClellan. Thank you very much, Mr. Malloy. Your letter from the Department to the chairman of the Senate Judiciary Committee, of course, will be made a part of the record, and we will have the benefit of that in the record as well as your statement today.

Senator McClellan. At the outset of your statement you emphasized the patent incentive as a consideration in procuring. What,

Dr. PRICE. I would like to start by mentioning that our society was founded in 1876, and it is the largest membership organization devoted to a single science in the entire world. It now operates on an annual budget of $17 million. It was incorporated in 1937 by an act of Congress of the United States under Public Law 358 and signed into law by President Roosevelt.

Our interest in presenting views on the subject before the committee today might be made clear by quoting the purposes of the society from our charter. These are, "that the objects of the incorportion shall be to encourage in the broadest and most liberal manner the advancement of chemistry in all its branches; the promotion of research in chemical science and industry; the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education, and attainments; the increase and diffusion of chemical knowledge; and by its meetings, professional contacts, reports, papers, discussions, and publications, to promote scientific interests and inquiry, thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

This is a quotation from the incorporation.

I personally support this mission of the American Chemical Society to help chemistry serve the American people and improve the general welfare.

I am sure that the general objectives of everyone participating in these hearings are undoubtedly similar, whether they are speaking for themselves or representing large organizations.

I think all of us want the United States to utilize its discoveries for the greatest benefit of its people.

But there are obviously honest differences of opinion as to the best way to accomplish this general objective. And we in the society have reviewed the proposed legislation which is before the subcommittee, and we would like to comment a little later specifically about S. 1809, sponsored by Senator McClellan; S. 1899, introduced by Senator Long; and S. 789, introduced by Senator Saltonstall.

We might say to begin with that we find the first two of these generally acceptable, but do not find that introduced by Senator Long acceptable in our view.

I would like to just say a word or two in the introduction about the interest of chemists in patents.

It seems to me from what has been said at these hearings and elsewhere that there are certain misunderstandings about the main purpose and significance of a patent. I would like to just interject that patents are of great interest to chemists. There are more chemical patents every year than there are any other single branch—I think some 22 percent of the patents are issued for chemical processes or products.

As the Constitution states, the purpose of the patents system is to "promote the progress of science and the useful arts." This is accomplished by encouraging the creation of useful innovations, by providing an environment of limited protection to the first to create new ideas, so that the inventor is encouraged to develop the bare idea to a

Suddenly, the Government needs this product, and so, realizing that this company has done considerable work already, goes to the company and says, "Here now, we have to have this as soon as possible—we need it. We are willing to give you a contract. You put your best men on it and get this thing done, get the breakthrough as quickly as you can."

And the company responds. Where are the equities? Who should get the patent rights on that patent when it breaks through and is accomplished? There is the difficult problem that we have. If you are starting from scratch, so to speak, and you make a contract to develop it and you secure the skills to do the research, certainly the Government would have it. But where the company has already made considerable investment, it goes out and employs people, mobilizes a lot of skills and talents, and it has developed those talents, as well as bringing them into a position where they are competent to pursue the objective—they have an investment in that, and the Government comes along and says, "Well, we are interested in this, too, so we will finance a crash program here, so to speak. We are very much interested. We will give you a contract for certain aspects of this. And we will furnish all the money from here on in."

There are some equities there on both sides. How are we going to distribute that equity?

Mr. MALLOY. Mr. Chairman, we feel that the equity in that situation would lead a prudent man to leave the title to the patent with the contractor. He has assembled some valuable assets, including both physical and human assets and prior research, so that he, obviously, has an investment in the situation. The Government obtains all that it requires when it gets a royalty-free license, to use or to have others use the inventions that might flow from the research work.

Senator MCCLELLAN. The Government has an inclusive right always.

Mr. MALLOY. I beg your pardon?

Senator MCCLELLAN. The Government would get a license for its purposes, in any event.

Mr. MALLOY. Yes, sir. It is a nonexclusive license, so that the Government can practice any invention or have any other contractor practice any invention for Government purposes anywhere throughout the world. So the Government gets everything it needs to get on with its business. We feel that the equities of the situation call for leaving title to the commercial application of the patent with the contractor. We think, also, that this carries out another primary and fundamental purpose, of the President's policy; namely, to get the invention working in the commercial marketplace. If the contractor has a degree of exclusiveness for a period of time, as provided for under the patent laws, it provides him with the incentive to actually bring the invention to the marketplace to make it available to everybody.

Senator MCCLELLAN. That is giving the patent away. If you give it to the contractor, the exclusive rights, subject to Government license to use it, that is giving away something. That is the way I interpret this. Woud you so interpret it?

Mr. MALLOY. Mr. Chairman, that gets to be a kind of a broad generalization.

You will recall that in my oral testimony I stressed the importance of distinguishing at all times between the situations in which the Government could plainly justify taking title to an invention, including taking title to any patent rights covering, or potentially covering, the invention and the actual ownership and exercise by the Government of right to exclude others stemming from those patents. I had pointed out that certainly it could not be contended that an invention or any rights thereto were immune from the operation of eminent domain, any more than a man's farm is, but I stressed that it was an essential of our political and social system that the exercise of eminent domain be for truly governmental purposes and not simply a strong-arm method of setting the Government up in a commercial enterprise.

Certainly if the National Institutes of Health, for example, were to contract for research intended to produce a cancer cure, it might logically require the dedication of the invention of such a cure, if made during that research, to the free use of the public. Let us suppose that the state of the art, as it may, leads one to surmise that cancer is the result of some virus action. Let us suppose further that one or two of our drug companies have, with respect of virus regulating drugs in other than cancer-producing areas, a substantial background of past experience and patents. Certainly it would be good sense for NIH to spend its research dollars, in part at least, in support of cancer virus investigations, in these well-staffed and well-prepared virus laboratories. Does it follow that all inventions may flow from that research in the areas of non-cancer-causing virus control, which are incidentally made, should also be dedicated to the public because the laboratories had received unquestioned assistance from NIH? I think clearly not.

Now to come directly to the point, let us suppose that because of NIH policy insisting upon such rights beyond the cancer program, these drug companies refused the NIH money but nevertheless, in the course of their normal work, a "windfall" invention is made, with all private funds, of a cancer cure.

If the expenditure of NIH funds for the discovery and public dedication of a cancer cure was justified as a proper governmental activity, does it not necessarily follow that the Government would be justified in taking over the privately invented cancer cure under the power of eminent domain, paying, of course, just compensation therefor? Would anyone assert that although the cancer cure might properly be taken from private hands, that the Government had any justification for taking ordinary inventions made simultaneously in the private program which resulted in the cancer cure?

We come back, therefore, to the situation that, as the association has repeatedly said, the patent system is premised upon the proposition that it affords the best means of promoting the progress of the useful arts in a private economy, just as does the private ownership of farms best promote agriculture in such an economy. Arguments which truly relate to the propriety of Government acquisition of private property by eminent domain do not belong in, and should not confuse the development of, a sound policy and we believe a private patent policy for procuring the exploitation of inventions arising in Government research in the commercial area.

I have taken the liberty of sending a copy of this letter directly to Senator Scott in view of the interest he exhibited at the hearing.

Respectfully,

W. BROWN MORTON, JR., *President.*

Senator MCCLELLAN. The committee will recess until 9:30 in the morning.

We hope to conclude with what we have scheduled before noon. If we can get through 30 or 40 minutes before noon, that much the better.

(Whereupon, at 3:20 p.m. the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, July 7, 1965.)

the rights to the patents which result from it without waiting to determine it later."

That question has been raised. Under what circumstances and why should we do that in the beginning, give away the patent? Why not wait until after the discovery had been made, and then settle the proposition?

The case that I gave you is an instant where, possibly, you would grant the exclusive right to the contractor at the beginning, is that correct?

Mr. MALLOY. Yes, sir.

Senator MCCLELLAN. And now one thing further that I can foresee, if the contractor is not to get it, and the Government has a policy where it will take all the discoveries and inventions, have exclusive title to them, there would be a disposition, I would think, on the part of the contractors as you said earlier, maybe not to put their best talents on this particular contract. And, secondly, maybe not to report discoveries made that were not apparent, in other words, let us take the side discoveries, that is, things that were discovered that you were not looking for, that were not necessarily pertinent to the contract, the product that is involved—they would not report those. But they would be required, I assume, under a Government ownership policy to report all of that, and the Government would become the owner of that, too. I can foresee that there might not be an enthusiastic inclination to report all those that were discovered.

Mr. MALLOY. I think both points are well taken. I think that there would be a reverse incentive against reporting in the other situation. It would be against the contractor's interest. Obviously, he would comply with the terms of his contract which requires reporting, but here again is an area of subjective judgment. In a borderline case, in which reasonable men might disagree, these things may not be reported, as you suggested.

Senator MCCLELLAN. How will this affect small business? You made some reference to that. If the Government policy is that of taking title to all patents, how will that affect small business, particularly with respect to incentives? Is an incentive a big factor in inducing small business to bid or to contract to work for the Government?

Mr. MALLOY. Yes, sir. I think that the small contractor needs the type of protection that we are talking about more than the larger contractor. Small contractors very often are the more inventive group, as a group, and the forces of economic competition are tougher on them. The protection afforded by the patent laws is even more important, I think, in this instance, than for the big contractor.

Senator MCCLELLAN. Well now, let us take another instance here where there is an extraneous discovery, something apart from the general objective of the contract involved in the situation that may have no particular use so far as the objective that the Government was seeking in financing it. If that is left in the contractor, if it has a commercial value, the contractor would naturally develop it, of course, but if it does have that commercial value and the Government takes title to it, then, as I understand the rigid policy of Government ownership of these things, the Government simply then makes it available to

"(B) The contractor has refused to license complainant on reasonable terms; and

"(C) Complainant is able to and will exploit the invention if a license is granted."

The clause we have suggested eliminates the necessity for administrative policing of all patents evolving from the R. & D. funds of each agency which would be time consuming and expensive. However, it does insure that a competent individual or firm can obtain a license if the contractor fails to exploit commercially inventions covered by such patents.

As a practical matter, the inclusion of the statement required by section 3(b)(7) will put private parties on notice as to the availability of a license if the patent owner does not exploit the invention, thus putting pressure on the patent owner to exploit the invention to prevent the issuance of a compulsory license.

Section 4(a) is also approved in principle, but the particular wording contains ambiguities which should be cleared up before the bill is enacted. It is suggested that the following language be used:

"Section 4(a). The agency head may require, at the time of entering the contract, that he be given the right to acquire, on behalf of the United States, an interest greater than the nonexclusive license specified in section 3(b)(2) in inventions if—

"(1) The purpose of the contract is to produce one or more end items, the use of which is or will be required by law or governmental regulation in furtherance of the public health, or safety, and the invention covers such an end item; or

"(2) The purpose of the contract is for the contractor to operate a Government-owned research or production facility, and the invention is especially adapted for use in that facility or in a related facility; or

"(3) The purpose of the contract is research, developmental, or experimental activity in a field of science or technology in which the Government is the sole developer or has provided substantially all the funds for research, developmental, or experimental activity in such field, and the invention is especially adapted for use in such field; or

"(4) The purpose of the contract is research, developmental, or experimental activity in a field of science or technology that is new, without any significant commercial or private history, and probably would not have been developed in the foreseeable future without Government financing, and the invention is useful only in such field.

"(b) Whenever the provisions of section 4(a) indicate that the agency head may acquire an interest greater than the nonexclusive license specified in section 3(b)(2), he shall acquire such greater interest unless he determines, after examination of the facts of the particular case, that special circumstances indicate that the contractor should retain rights in the invention greater than the nonexclusive license specified in section 4(c), including rights in foreign patents, subject to the interest reserved to the United States in section 3(b)(2), and that the public interest would not suffer as a result of the contractor retaining such greater rights."

There are several minor differences in wording in the foregoing and two changes of some importance. In section 4(a)(1) the reference to "commercial use by the public" has been deleted since it is believed that that term is so broad and comprehensive that it could be construed to cover substantially all inventions, a result obviously not intended by the Presidential memorandum in which the language first appeared.

In addition the phrase in section 4(a)(3) referring to the acquisition of exclusive rights has been deleted as superfluous.

A new paragraph 4(b) has been added more clearly to delineate the procedure under the unnumbered paragraph appearing in section (4) of S. 1809 immediately after paragraph (a)(4).

Section (4)(b) is approved without change.

Section (4)(c) is not endorsed by APLA. In view of the preceding language in sections 3 and 4, it is believed that all the parameters involving patent rights are so clearly delineated that section (4)(c) is superfluous. It can have two bad effects: first, to provide an easy way to avoid making a determination under section (4)(a) and (4)(b); second, to increase the ultimate burden on the Gov-

In most other situations, the President's policy calls for the Government to take a license at the time of awarding the contract.

Senator McCLELLAN. Particularly, in the field of medicine, if the Government contracts with a university or with some institution, a nonprofit institution, to do research work, certainly, in my judgment, as I view the situation now, the Government should take title.

Mr. MALLOY. That is now the normal situation.

Senator McCLELLAN. And it does that now?

Mr. MALLOY. Yes, sir.

Senator McCLELLAN. Now, suppose that the Government, let us say, writes a comparable contract, let us say, to some chemical company, to do research within a given field, such as cancer, heart, or a similar disease, trying to find a remedy—who should have the patent rights in that contract?

Mr. MALLOY. In that situation, Mr. Chairman, the President's policy calls for the Government to take the title.

Senator McCLELLAN. That is, the title to what the Government is seeking? If they found a remedy, let us say, in the medicine that was useful for that given purpose, very well. But suppose an extraneous finding is made, something wholly unrelated in doing the research for cancer—suppose they found some medicine in that process that cured some other disease, something wholly unrelated to the general objective—to whom should that patent go then?

Mr. MALLOY. It is my understanding, Mr. Chairman, that in that situation title would, also, be with the Government.

Mr. JOHNSON. May I amplify that answer a little bit?

Senator McCLELLAN. Maybe we ought to ask the Department of Health, Education, and Welfare about it.

Mr. MALLOY. I think that is more in their area. The Department of Defense has some contacts in this area but it is a very small part of our business.

Senator McCLELLAN. Go ahead.

Mr. JOHNSON. There may be some cases in which the contract was not intended for a public health purpose. However, in the course of performance an invention is made which proves to have application directly in the health field. In that case, under the President's policy, the Government would have acquired a license sufficiently broad to permit the use of that invention, if necessary to fulfill health needs. In other words, if you were to have a cancer cure developed under a petroleum contract it would be possible to have a license to permit that cancer cure to be made available as rapidly as possible. That is spelled out in the President's patent policy.

Senator McCLELLAN. Another item, you oppose the Government making a renegotiation of a patent right, I believe. You expressed opposition to that. You do not think that the Government should have the right to do this?

Mr. MALLOY. Not in the terms that are included in S. 1809, Mr. Chairman. We think that the bill goes too far. There are provisions in the President's policy which we think amply protect the Government's needs. There are the so-called march-in rights whereby we can, even though we have contracted to leave title to the patent with the contractor, we can come back later and require compulsory licensing

governmental purpose. But we see a fundamental distinction which we feel has been overlooked by many people in this field between acquiring an invention and acquiring and exercising the exclusive rights in a patent on an invention.

Now, generally speaking, Government research is not and should not be intended to produce inventions having commercial application. It is intended to produce inventions, largely inventions which would not be made except for Government intervention—that is, they are threshold inventions, or to use a term——

Senator McCLELLAN. Well, that would be true as in the Defense Department, possibly. But that would not be true in the medical field, would it?

Mr. MORTON. If I may say, I think it would, sir. It seems to me that in the field, for example, of improved bandages, we can relax and let the commercial enterprises take care of that. In the field of a cancer cure, where breakthrough inventions are necessary, no doubt Government funds are justly expended.

Senator McCLELLAN. We have a rollcall vote. Do you have more that you wish to tell us?

Mr. MORTON. Only this. We feel that the compulsory license aspects of the revisions we have suggested in S. 1809 could well be analogized to the military draft.

It is noticeable, I am sure, to the Senate as well as to the rest of us, that the existence of the draft tremendously promotes volunteering. We think that the existence of the compulsory license prvoisions, even though they seem a little rigid in their application, will largely eliminate the necessity of proceedings under them, that there will be a free exploitation of inventions made by virtue of the adoption of these provisions without the necessity of going through all that litigation.

Senator McCLELLAN. Thank you very much.

(The prepared statement of Mr. Morton follows:)

STATEMENT ON BEHALF OF THE AMERICAN PATENT LAW ASSOCIATION

The position of the American Patent Law Association with respect to Government patent policy is set forth in the following resolution adopted by the board of managers of the association in the spring of 1964:

"Whereas it is the position of the American Patent Law Association that progress of the useful arts is best promoted when inventors are made secure 'in the exclusive right to their * * * discoveries,' because the protection of such exclusive rights affords a vital incentive to private enterprise to assume the economic risks involved in developing new products, in introducing them to the public, and in promoting their use; and

"Whereas it is the conviction of the American Patent Law Association that Government authority cannot and should not undertake the introduction and exploitation of new products in the public marketplace in competition with private enterprise;

"Whereas the American Patent Law Association is duly appreciative of the positive steps taken during 1963 to solve the complex problems leading to a uniform Government patent policy as embodied in the President's statement of Government patent policy (of October 10, 1963), the McClellan bill, S. 1290, the Saltonstall bill, S. 1623, the Toll bill, H.R. 4482, and the Daddario bill, H.R. 471, and has made an intensive study of the statement and the several legislative proposals: now, therefore, be it

"*Resolved*, That it is the policy of this association that where the Government of the United States seeks to avail itself of the skill, resourcefulness, and creative ability of private enterprise, and enters into research and develop-

This is another thing that you cannot prove with great mathematical precision, but this has been of great concern to the Department for many years and the officials of the Department have this concern today.

Senator McClellan. Who suffers under these the most, the Government's interest, or the public's interest or the contractor's interest, if S. 1899 is adopted—which suffers the most?

Mr. Malloy. Whose interest would suffer the most?

Senator McClellan. Under the provision, the Government takes title to all and where the Government takes it in the interest of the public, primarily, because that is the only reason for the Government's taking title, because public funds have paid for the research, No. 1—No. 2, the Government, even where the patent rights remained in the contractor, the Government takes a license for its purpose—so it is the public interest, and the contractor's interest, the private enterprise system interest that is involved. Now, which would suffer the most, ultimately, under the provisions of S. 1899, if we enacted that into law?

Mr. Malloy. Mr. Chairman, it would be my view that the Government's interest would suffer the most, and for the reasons that I just indicated, that we would, probably, not be able to get our research program handled by the very best research contractors.

Now it is also, of course, true that a contractor would lose an advantage as well if the Government had title, but the contractor would not necessarily have to place himself in that position. He could avoid the problem by avoiding the contract.

Senator McClellan. I think that what we have tried to do here, with due diligence to our free enterprise system which we do not want to destroy or unduly or unnecessarily impair—where the Government spends money, the public interest becomes involved—it is public funds that are being expended—so that I think that in trying to resolve a delicate and complex issue such as has arisen here, it would be well for us to consider not just the initial equities and advantages that one may get or the other may get, but what is going to be the long-run, overall impact upon the public interest and upon the free enterprise system, and your conclusion is that, ultimately, the public interest would suffer the most?

Mr. Malloy. Yes, sir, Mr. Chairman.

Senator McClellan. Precisely and concisely as you can, please state why.

Mr. Malloy. The President's policy tries to weigh this delicate balance and come up with a solution. The issues that were involved were first, how to get the best performance under Government research and development contracts, and, second, how to get the most benefit for the public from the fallout benefits that result from the spending of Government money on research and development. Our feeling—I know that it is the thinking behind the President's policy as well—is that we are able to get the best research and we are able to bring to the public, through the incentive provided by the patent itself, these spinoff benefits better by leaving title to the commercial application with the contractor.

Mr. QUIGLEY. And I think rightly so. It does not strike me as the fair thing to do. As I say, it does not particularly involve our Department and its mode of operating.

Senator SCOTT. You and I have been engaged in many perilous operations over the years, and I want to thank you very much, Mr. Secretary.

Mr. QUIGLEY. Thank you, Senator. We will supply for the record the information you have requested. If for some reason or other we cannot run the 18,000-some grant applications through the computer and come up with that answer, we will report that fact to you.

Senator SCOTT. All right. Thank you. And thank you, Mr. Chairman.

Senator MCCLELLAN. All right. Thank you very kindly. Our next witness is Mr. Morton. Mr. Morton, you may identify yourself, please, sir.

Your statement will be printed in the record and you may highlight it if you wish. You represent the American Patent Law Association?

STATEMENT OF W. BROWN MORTON, JR., PRESIDENT, AMERICAN PATENT LAW ASSOCIATION

Mr. MORTON. Yes, Mr. Chairman, I am president of the American Patent Law Association at the present time.

Senator MCCLELLAN. Very good.

Mr. MORTON. I have over the years devoted some attention to this subject. I have reviewed the statement. It correctly expresses the long-considered policy of the association.

I am pleased to see that it meets the chairman's suggestion of specific suggestions for amendment to the bill. It has specific suggestions embodied in it, Mr. Chairman, for language changes in S. 1809 already in the statement.

Senator MCCLELLAN. Very well.

Mr. MORTON. I think to highlight our position I will refer to what the statement says on page 3 in the next to the last paragraph.

It seems to us that a great deal of the discussion of this subject has turned on whether the Government gets what it pays for. It obviously is entitled to get what it pays for. It seems to us the Government, by the policy personified by the Long bill, and various Long amendments to specific instances of Government research legislation, is insisting on getting more than what it pays for. Perhaps that is what Senator Scott has in mind with the reference to fallout inventions.

Let me give you an example, if I may, that has occurred to me of what I have in mind.

Let us suppose that the Government wants a radio set specially designed to function well under the damp conditions of the jungles of Vietnam. It applies to a contractor to jungleize a radio. The contractor puts his best men on it. Under the criteria laid down ordinarily in these Long bills, for lack of a more generic term, the contractor, if the invention is made during the course of the work done on the contract—has to turn over title to the Government.

Senator MCCLELLAN. Now, the fallout, so to speak.

research work. Company B has had years of experience in this particular area—has not quite succeeded in getting a breakthrough. And so they enter into that contract for a consideration. And they do develop something. They do make a finding. Is it true in the commercial world that company A obtains all of the patent rights?

Mr. MALLOY. It is not nearly as clear as to what is the normal practice between two commercial concerns in the situation you have described. It is my understanding, actually, that the more usual practice would be that company A would not ask and not receive title to inventions discovered in the performance of this contract. This is by no means an across-the-board type of conclusion.

We made a survey some years ago, I believe it was for the Senate Small Business Committee, and found that the practices of the Department of Defense contractors were pretty generally against taking title to patents in your situation, but that there were some exceptions. Where company A was intimately involved itself in the development of the particular item, had invested a lot of its own know-how and money, then it might ask for title in those circumstances.

So to sum up the generality, as I undertsand it, in commercial transactions, the company placing the research contract does not request or get title to the patents that are developed by the other concern. This is because commercial companies are not normally in the business of inventing for other companies. The exception, I guess, to this would be companies that are in strictly research business—they are in the business of making their talents available to other corporations and have no objections whatsoever to giving up titles to any inventions, primarily because they are not in the business of exploiting them.

Senator BURDICK. Maybe I did not make myself clear. This is a case where company A hires or contracts with company B to do research work for company A.

Mr. MALLOY. Right.

Senator BURDICK. They pay them under the contract. Is it your testimony that company A does not retain the patent rights?

Mr. MALLOY. Not normally.

Senator BURDICK. Not normally?

Mr. MALLOY. Yes, sir.

Senator BURDICK. That is news. There has been testimony to the contrary.

All right, you testified here a few minutes ago that under S. 1899, the public interest would suffer most, because there is not a proper balance. Is that what you said? If S. 1899 were adopted and all patent rights went to the Government, you said that the public would suffer most because it was not a proper balance of equity. Let me call your attention to page 21, line 20—you have a copy of S. 1899 before you?

Mr. MALLOY. Yes, sir.

Senator BURDICK. Let me read it to you:

Under such regulations in conformity with the provisions of this section as the Administrator shall prescribe, he may waive all or any part of the proprietary rights of the United States under this act with respect to any invention which has been made by any person or class of persons in the performance of any

private foundation, in which case it would be unfair and inequitable for the Surgeon General to exercise the Government's right.

Senator SCOTT. That would indicate, then, that HEW believes these other groups, if they help to finance the cost of an invention, would have the right to share in the patent.

Mr. QUIGLEY. Very definitely, Senator. This is not on policy now, but as I indicated, our regulations in this area are under review.

Senator SCOTT. Do you have any information, even roughly, as to how many NIH grantees also receive financial support from non-Government sources?

Mr. QUIGLEY. I do not know that we have any such figures. If we have, we would be happy to supply it for the record.

In my own judgment, I think it would be a substantial number, because I think some of the better researchers are likely to attract support from a variety of sources.

(The information referred to follows:)

We have tabulated the information reported in question 6-B-1 of the Public Health Service application form 398 from the 3,467 applications reviewed by study sections in the June cycle. Two exclusions were made: support from the "own institution" of the investigator and support from Federal agencies. The data, therefore, reflect the proportion of investigators who have research support from others and than his own employing institution or the Federal Government.

Principal investigators with "outside" support

Number of "other" sources	Principal investigators	
	Number	Percent
0	2,659	76.7
1	603	17.4
2	142	4.1
3 or more	63	1.8
Total	3,467	100.0

Senator SCOTT. Now, I understand that NIH in the grant application that each investigator must fill out asks for detail and specific information—"All other research support." The investigator is asked to state the title of his research project, the amount, and the amount of time he is spending on the project. Now, this is question 6-B on the grant application.

If you have been obtaining this information from all the NIH grantees, could you not run this information through one of the Department's computers and give us an answer to that?

Mr. QUIGLEY. Probably we could. Offhand I know of no reason why we could not.

Senator SCOTT. I do not know much about computers, but I am prepared to assume they can do almost anything.

Mr. QUIGLEY. I think we will move forward on that assumption. If we prove to be wrong, we will be back to say it could not be done, for whatever reason.

Senator SCOTT. I think it would be helpful—to determine the extent of multiple sponsorship of research in the medical field, measure

impose its requirements on top of the work that has already been done at the private expense of the particular contractor. The contract might be for a very small amount. And if he were to give up his commercial rights for a very small consideration he would, I am sure, think twice about it, and his board of directors would be quite concerned about that situation, too. But in your example, I do not think that there would be any doubt but that the best talents would be applied to the job.

Senator BURDICK. I do not think that any segment of American business enters into a contract, let us say, at the cost of 7 percent that would not do its best in such a situation.

Mr. MALLOY. I would hesitate to say that they would not do their best, because I do not know that this can be proved one way or the other. But in that situation a particular contractor, for the reasons we have stated, may not want to enter into the contract with us in the first place. I think that if he did, I would, certainly, not want to say that he would do less than his best, except in those situations in which human nature might take a hand and the incentive would be against the application of the best ideas.

Senator BURDICK. A transaction for research and development in a contract is at an agreed upon figure, ordinarily?

Mr. MALLOY. Yes.

Senator BURDICK. That is an incentive in itself, is it not?

Mr. MALLOY. What is that?

Senator BURDICK. That is a piece of business in itself?

Mr. MALLOY. It certainly is.

Senator BURDICK. Which most American business would honor and perform?

Mr. MALLOY. Yes, sir; that is right.

Senator BURDICK. Do you know of any instances in the Defense Department where a contractor has refused to enter into a contract, where he was denied patent rights?

Mr. MALLOY. No, sir; I know of no such instance. I suppose that in our experience that has been true more because we have not had in the past a policy of taking title. We have left title to inventions with contractors and have not really had the problem, so that we are looking ahead really and speculating as to what might happen if there is a radical change in the patent policy.

Senator BURDICK. That is a speculation. But according to history and facts there has not been anybody who has refused to do the work?

Mr. MALLOY. I know of none, Senator Burdick. I suppose that there might be some, but as a generality this has not been a problem in the past with the Department.

Senator BURDICK. Well then, the closing question, then you think that the taxpayers in this work—it is just that simple, is it not—would not lose?

Mr. MALLOY. Senator Burdick, I think that, as with all of the questions that are before us in this consideration of patents, it tends to be an oversimplification. I think that this is the easiest thing to do in this field. I think that is, possibly, one, because as I indicated before, it stands on certain presumptions that are not necessarily true.

Senator BURDICK. What is the answer to my question then?

PHS grant (one of five sources of support), was assigned to the University of California under its agreement with the Public Health Service in order that it may issue an exclusive license for development of the invention. It issued an exclusive license for 5 years to Lederle Corp. This invention was covered by 10 patent applications under which a license was executed to the Government in 1958. The university subsequently assigned all of its rights to the inventor, Dr. Penn, which assignment, in the opinion of the Public Health Service, was in violation of its 1953 agreement with the university and it institutional agreement which postdated the 8.2(b) determination by 2 years (institutional agreement was entered into March 21, 1955). After considerable correspondence it was determined that one application was still pending in 1962. The University of California subsequently admitted its error in abandoning to the inventor these inventions which they considered worthless. Since the inventor had left the country and was then in India, there was little that could be done to rectify the error. Dr. Penn had licensed the California Corp. for Biochemical Research on an exclusive basis for the life of the patent. There is no information in our file with regard to either the commercial development, if any, of the drug, or its effectiveness.

2. On September 26, 1955, an invention "Low Noise Amplifiers for Use in X-Ray Screen Intensifiers of the Television Type System for the Translation of Intelligence at Low Signal to Noise Ratios" was made at Johns Hopkins University, with some support from a PHS grant, by Dr. Russel H. Morgan and Ralph E. Sturm. The circumstances in this case were unique:

(1) The inventors had been working on this invention over a long period of time while pursuing graduate and postgraduate work, contributing much of their own funds prior to PHS support.

(2) Although sizable contributions were also made by the university, the university did not wish to administer the invention and felt that equity called for assignment to the inventors.

(3) Patenting and exclusivity were necessary to bring this complex scientific discovery to the market. Attempts to interest several commercial organizations in marketing this invention, useful in hospitals and other medical agencies, were unsuccessful.

(4) Additional expensive developmental work was required on this complex electronic device which would be undertaken only by someone assured of long-term exclusivity.

A determination was made by the Surgeon General on September 26, 1955, and amended on November 18, 1955, permitting the inventors to retain rights to the invention covered by two patent applications and to sell or license the patent applications to a commercial corporation which in this case was Bendix Aviation Corp., subject to conditions that may be imposed by the Department of Health, Education, and Welfare. The Government reserved a license (nonexclusive, irrevocable, and royalty-free for all governmental purposes). It approved the agreement between the Bendix Corp. and the inventors which included amount of royalties to be charged. The Government required that Bendix Aviation Corp., after 10 years from April 5, 1955, make the invention available through nonexclusive licensing of other manufacturers in the fields of medicine and public health, the royalties not to exceed 5 percent. Bendix agreed to give priority to development in these fields. If, after development of the invention to the point of utility and satisfactory quality, Bendix could not meet the demand, in any field, it would be required to nonexclusively license other qualified manufacturers at royalties not to exceed 5 percent. No royalties were to be included in the price of any sales to the Government by Bendix or by any assignee or licensee.

3. On September 8, 1959, a determination was made to assign an invention entitled "Air Pollution Testing Instrument for Measuring Pollution in Gases" invented by Addams, Koppe, and Dana under an air pollution contract with Washington State University to the contractor for development and administration. It was proposed that the college would give a 5-year exclusive license to an interested, reliable manufacturer under terms which "would insure the continued and rapid production of a satisfactory product). At the termination of the 5-year period licenses would be "available to all manufacturers on a nonexclusive royalty licensing basis." Subsequently, the college concluded that patenting would be uneconomical and the invention became unpatentable as a result of its prior publication. A supplemental determination was written reflecting the situation.

of rights to the results of such research, and a summary of our recommendations concerning the three measures under consideration by this committee.

As you are aware, constituent agencies of the Department engage in and support research in the life sciences, social sciences, and the physical sciences.

The major portion of our research is medical research and is carried out through the grant mechanism rather than through contract. Also, a very considerable amount of medical research is carried out intramurally in such facilities as the National Institutes of Health, our Communicable Disease Centers at Savannah and Atlanta, Ga., and the Taft Sanitary Engineering Center at Cincinnati, Ohio. The total research budget of the Department for fiscal year 1965 totaled $735 million.

Consistent with the Department's statutory responsibility for the advancement of secience and knowledge and the dissemination to the public of the results of research, it is the general policy of the Department that the results of Department-financed research should be made widely, promptly, and freely available to other research workers and the public, by publication and by royalty-free licensing under protective patents or by dedication of Government-owned inventions, though our regulations permit of some exceptions to this where the public interest in achieving the development and practical application of inventions can best be promoted through other means. I might add, in this connection, that our regulations on this subject have been and are under intensive review within the Department to assure that they are effective to accomplish the wide, prompt, and free availability of scientific advances to all segments of the public.

In this context, we regard the provisions of S. 789 now before this committee as wholly incompatible with the Department's research objectives and our current policies and practices. The basic premise of the bill, that the Government should normally acquire only a nonexclusive license for governmental purposes whereas the contractor or grantee shall acquire ownership, is at odds with our concept that the taxpayer is entitled to the fruits of research financed by tax funds. Those provisions contained in the bill under which the Government might acquire more than such a license would not generally be applicable to situations in which our Department is likely to be involved. Moreover, the procedural requirements incident to governmental acquisition of greater rights are so cumbersome as to render illusory the opportunity of the Government to acquire more than a license. We are, therefore, opposed to the bill and urge that it not be favorably considered.

S. 1809, on the other hand, reflects, in the main, the criteria set forth in the Presidential statement on Government patent policy issued in October 1963. Insofar as it would apply to our research activities, the bill embodies the principle that, in general, the Government should acquire rights to inventions resulting from Government-financed research for the benefit of all the people and, of course, we firmly endorse that policy. However, even apart from certain departures in the bill from the criteria contained in the President's statement, we believe that more experience under the statement is

ment, which will make the invention freely available to all for commercial as well as governmental purposes. If A does not take the contract, its exclusive commercial position will be preserved and the existence of the patent may enhance its chances of getting a production contract from the Government after B has developed the item under the Government research and development contract. In any event, A can recover just compensation from the Government for B's work and also if the Government production contract goes to another. In this type of situation the policy of the Long bill would definitely discourage the qualified company from taking the contract, but the inexperienced and less qualified company would find it less objectionable.

The philosophy implicit in S. 1899 that the incentives of the U.S. patent system should be excluded from Government contracts should and must be rejected.

S. 1047

This subcommittee is also considering S. 1047, introduced by Senator Williams, to amend section 1498 of title 28, United States Code.

The AIA presently opposes any basic change in the principles of section 1498, and therefore cannot support S. 1047. However, we do favor legislation giving patent claimants easier access to the courts in pursuing claims against the United States. For example, a patent claimant could be permitted to bring such in his "home" district, or circuit, or the Court of Claims system could be enlarged to permit trial before a commissioner in the claimant's "home" district.

The Aerospace Industries Association appreciates the opportunity to present its views and, as in the past, stands ready to offer any assistance deemed necessary or desirable by this subcommittee.

Mr. SHELTON. If there are any questions, I would be happy to try to answer them.

Senator MCCLELLAN. Well, I have asked you the principal one.

I had requested the other witnesses who preceded you to submit the proposed amendments, and I see that you have done that in your prepared statement.

Mr. SHELTON. Yes, sir.

Senator MCCLELLAN. These are the amendments here that you would recommend.

Mr. SHELTON. Yes, sir.

Senator MCCLELLAN. And you spell them out and have prepared them in the language you think appropriate.

Mr. SHELTON. That is correct, sir.

Senator MCCLELLAN. Very good. Thank you very much.

Senator Scott, any questions?

Senator SCOTT. No questions.

Senator MCCLELLAN. Well, thank you, sir.

Mr. SHELTON. Thank you.

Senator MCCLELLAN. Mr. Quigley, will you come around again, please.

STATEMENT OF JAMES M. QUIGLEY, ASSISTANT SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY MANUEL B. HILLER—Resumed

Senator SCOTT. I appreciate your standing by to enable me to get back.

I had a few questions I wanted to ask.

I understand from time to time the NIH grantees have invented new chemical compounds having a potential value as a new drug. That is right; is it not?

to question seriously whether the advantages of consistency which such a centralized arrangement might provide would not be outweighed by the disadvantages. Of perhaps even more serious import are the provisions of section 7(a) which would make the Federal Inventions Administration the agency principally responsible for the receipt, storage, and dissemination of scientific and technical information deriving from research and development activities of Federal agencies and their grantees and contractors. There already exist organizations responsible for the collection and dissemination of technical information, for example, the Science Information Exchange, the Clearinghouse for Federal Scientific and Technical Information, and the National Library of Medicine. Apart from the question of the duplication of such resources and repositories of information, there is raised the question whether the provisions of the measure would result in an undesirable diversion of scientific and technical information away from traditional sources.

Section 7(b)(2) provides for the evaluation of scientific technical information available to the administration to determine its probable application to commercial uses in the development of new and better products and advanced technological methods of production. For one Government agency to assume the monumental undertaking of evaluating the results of all research as to their suitability for commercial uses, a task which is now performed on an ad hoc basis by industry and the entire scientific community, would be prohibitive in terms of appropriations and the manpower needed to perform such a task.

In summary, Mr. Chairman, we believe that further experience under the existing policies laid down in the President's statement is desirable. However, if comprehensive legislation is to be enacted at this time the chairman's bill, S. 1809, would in our opinion be the appropriate vehicle if amended along the lines suggested in our report.

This, Mr. Chairman, concludes my summary, and I shall be glad to answer such questions as you may have.

Senator McCLELLAN. Thank you very much for your statement.

If I understand, you sum up your presentation by saying you do not think any legislation should be enacted right now, that we should wait for further experience under the President's directive.

Mr. QUIGLEY. In essence, Mr. Chairman, this is our position.

Senator McCLELLAN. That is No. 1. And No. 2—if a bill is to be passed, you think S. 1809 offers the best vehicle at this time, and you would recommend it only, though, if it is amended.

Mr. QUIGLEY. That is correct, Mr. Chairman.

Senator McCLELLAN. Along the lines of your suggestions.

Mr. QUIGLEY. Of the three bills before the committee, we would endorse—come closest to endorsing S. 1809 because we think it comes closest to the President's statement of October 1963. We would like to bring it even closer to that.

Senator McCLELLAN. Well, not just because it may conform to some Presidential directive—but it is the merit of it we want. What we are seeking here is what legislation is best.

While it may come nearer to conforming to the President's directive than the other bills—unless you wholeheartedly support the directive and think it provides the solution and the best policy—if so then all we need to do is adopt the Presidential directive.

S. 1809

As stated above, we endorse S. 1809. However, to clarify, strengthen, and facilitate the administration of the bill, we offer the following proposed changes or amendments:

1. In several places S. 1809 refers to the agency head acquiring for the Government "the principal or exclusive rights" in inventions. This same language also appears in the President's statement on Government patent policy, and certain executive departments have construed it as meaning title in every case. We think the bill intends this expression to be broad enough to include title, but not to be limited thereto. Also, we do not believe that the Government really needs to acquire title to a patent in order to fully protect the public interest. To clarify the meaning of this expression and to provide adequate and flexible guidelines for the various Government agencies in promulgating regulations to the end that they will not speak only of title, we suggest that a new paragraph (i) be added to section 2, after line 13 on page 3, reading as follows:

(i) *The term "the principal or exclusive rights" means, but without limitation thereto, either*

1. *title, or*
2. *exclusive license, subject to section 3(b)(3), or*
3. *an undivided part ownership of the patent with the contractor, or*
4. *a nonexclusive license with the right to grant sublicenses, or*
5. *a nonexclusive license with the right to compel the granting of licenses to others on reasonable terms.*

2. Amend section 2(c) by adding after the word "contract" on line 15 of page 2, *which has as a purpose the conduct of experimental, development, or research work.*

This proposed amendment is to conform the first and second sentences of section 2(c) and to conform section 2(c) with section 3(a).

3. Amend section 3(b)(2), lines 6, 7, and 8 of page 4, by deleting "or by a foreign government pursuant to any treaty or other agreement with the Government of the United States."

Because of provisions in current bilateral agreements between the United States and certain foreign countries, the present language of section 3(b)(2) would automatically convey a license to foreign governments under contractor-originated inventions whether or not the United States receives reciprocal rights from contractors to foreign governments. To our knowledge no foreign country has enacted legislation (of the type proposed in S. 1809) to implement article V of the standard bilateral agreement (study No. 24, Patent and Technical Information Agreements, 86th Cong., 2d sess., pursuant to S. Res. 240, 1960). Hence, any foreign citizen who owns a U.S. patent can assert it against the U.S. Government. We believe that either the U.S. Government or the contractor should receive a quid pro quo for such licenses rather than the Government giving them away as would result from the present language of 3(b)(2).

4. Amend section 3(b)(3) by adding after the word "invention" on line 12 of page 4, *together with the right to grant sublicenses thereunder to the extent the contractor was legally obligated to do so at the time the contract was awarded.*

This is merely to permit the contractor to honor his existing legal obligations and is wholly in keeping with the Government's objective of working inventions.

5. Amend section 3(b)(8) by inserting after the word "knowingly" on line 12 of page 6, *and with intent to defraud the Government.*

We agree that if a contractor deliberately and for the purpose of defrauding the Government withholds a disclosure, there should be a penalty. Our concern here is that the present language could be construed broadly enough to punish an honest error or a mistake of judgment.

6. Amend section 8(b) by inserting after the word "head" on line 3 of page 15, *shall make all patents acquired under this Act on behalf of the United States freely available to the general public of this country and, in addition* * * *

In lines 3, 4, 5, and 6 strike "an exclusive * * * of the United States" and substitute, *licenses to others under any such patents.*

The foregoing changes to section 8(b) would make this bill consistent with our views expressed below on the subject of the Government having title to patents.

Unfortunately some patented inventions, particularly those requiring a substantial investment to adopt them for public use, may not reach the commercial

deeply interested in the subject, who have a responsibility in this field, and who are experienced and are capable of giving us counsel.

Thank you very much.

Do you have any questions, Mr. Brennan?

Mr. BRENNAN. Mr. Quigley, are you acquainted with the patent amendment that was offered on the Senate floor last month to S. 596?

Mr. QUIGLEY. Heart, stroke, and cancer—yes, I am generally familiar with it.

Mr. BRENNAN. Did the Department support that amendment? There was some confusion during the Senate debate as to what the position of the Department was. Could you clarify this for the record?

Mr. QUIGLEY. Well, to that end, and I hope I suceed—I think the position of the Department was that if an amendment along those lines was to be adopted, this amendment, as it was sponsored by the Senator from Louisiana, was acceptable to the Department. This was an amendment to an amendment. It was worked out from the original proposal by Seantor Long. We indicated that if the Senate and the House were to adopt a measure along this line, we felt we could live with this in these particular areas of research.

Senator MCCLELLAN. You want to submit that as an amendment to that, or do you want to submit a revised version?

Mr. QUIGLEY. I think a revised version, because I think more appropriately this would go as an amendment to Senator Long's bill rather than as an amendment to the chairman's bill. But I think somewhere in this direction would be the thrust of any amendments we would suggest.

Senator MCCLELLAN. I want everyone to be free to offer their best judgment on this, and be as helpful as possible.

Mr. BRENNAN. Mr. Quigley, do I correctly understand your statement to indicate that the Department's position is that the Department favors a mandatory requirement that you must acquire patent rights in all inventions relating to public health?

Mr. QUIGLEY. No; you are not correct in that, and I think this is where we parted company with the original proposal by Senator Long.

Mr. BRENNAN. So you are not supporting, then, the amendment that was offered on the Senate floor?

Mr. QUIGLEY. I think we indicated that if an amendment was to be adopted to the bill, that in our judgment this was far preferable to the original proposal. I think our issue with Senator Long's proposal has been the mandatory requirement—despite the fact that as a general proposition, as a general policy, in our areas of research, health, and welfare, we think generally this is a good approach—but we think there ought to be enough flexibility within the Administrator to make exceptions in exceptional cases, the Government not taking title—that would best promote the common good.

Mr. BRENNAN. So the Department then would prefer to retain some measure of discretion?

Mr. QUIGLEY. That is correct.

Mr. BRENNAN. Thank you.

Senator MCCLELLAN. All right. Thank you very much. If you will submit the amendments to us here, we will be glad to weigh them.

try conducts its own business—on the theory that whenever industry goes to another company for a research and development job, it requires that particular company to assign title to inventions and patents to the contracting company. This is not the general practice of industry. I do not mean to say that industry never does this, but the general practice is that it does not require title. And the reason for this is a very simple one.

In the first place, if you contract with a manufacturing company for them to do some research and development work in their field, and you tell that company any inventions that they make have got to be assigned to you, we know that we will pay through the nose for the assignment of those inventions, because that company is just not going to want to assign these, and it is just not worth that much money.

In other words, the main interest of manufacturing companies is the production and sale of goods. It is to further that interest that they perform research and development work and the profits on such efforts are a secondary consideration. To such companies, the right to retain title to any inventions they might make in the performance of a research and development contract is valued very highly, because there is always a chance, no matter how slight, that an important invention having significant value to them in their business will result if they devote their very best efforts to the work. For this reason, industry would have to pay such companies a great deal more for research and development work with title to patents than for such work without title to patents.

Moreover, because the likelihood of any company making inventions of significant value in the performance of R. & D. is totally unpredictable at the time of contracting and occurs relatively infrequently, industry realizes that in contracting for R. & D. with any company to which title to patents is important, it gets much more for its R. & D. dollar, and better contractors too, if it does not demand title to patents.

So I would say that this statement, that the Government is merely trying to negotiate with business on the same basis that business negotiates with itself, is not a correct statement.

Mr. Chairman, I have kind of skipped around. I have not done much reading of this statement. But it is all in the record.

Senator McCLELLAN. Yes. Your statement may be printed in the record in full.

(The prepared statement of Mr. Shelton follows:)

STATEMENT OF THE AEROSPACE INDUSTRIES ASSOCIATION

My name is Charles L. Shelton. I am director, patent section, of the United Aircraft Corp. but appear today representing the Aerospace Industries Association of America, Inc. (AIA). I have served as chairman of the patent committee of the AIA, and presently am the chairman of the Federal patent policy subcommittee of that committee. My statement before the subcommittee is an expression of the position of the Aerospace Industries Association on the matter of a Federal patent policy.

The membership of the association is composed of the principal manufacturers of aircraft, spacecraft, and missiles, as well as their powerplants, guidance systems, and components. Our members are engaged in commercial markets as well as in contracts with many Government agencies and have had long expereice in the field of research and development. Approximately one-

Senator Russell B. Long on the one hand, and S. 1809 and S. 789 introduced by Senators McClellan and Saltonstall respectively on the other.

The Long bill is obviously based on the assumption that a policy of the Government taking title to patents will not interfere materially with procurement by the various Government agencies in making the types of contracts which are necessary to enable them to meet their responsibilities in achieving the missions for which they were created. In this day and age when technological progress is so vital to the defense and well-being of the country, this is not only a very dangerous assumption to make, but evidence already before this subcommittee as well as the Committee on Science and Astronautics of the House clearly indicates that such an assumption is wholly unjustified.

The establishment of a rigid Government-take-all patent policy such as Senator Long proposes would tend to make industry shy away from Government contracts.

Senator McCLELLAN. I am going to depart from my usual procedure here and ask you some questions as we go along, if you don't mind.

Mr. SHELTON. I would much prefer that, sir.

Senator McCLELLAN. You say a Government-take-all patent policy would tend to make industry shy away from Government contracts.

If the Government pays on a cost-plus basis, or the contract provides for a reasonable profit for the work actually done, and for what the Government gets or expects to get, why would contractors or industry shy away? I don't quite understand.

Mr. SHELTON. Well, this is because, Senator, in cases where a particular company has invested its own money in research and development and has established a position in a particular art with its own money, and if it then takes a Government contract in which it is required to give the Government title to patents for inventions which are made under that contract, this will prejudice its commercial position.

Senator McCLELLAN. Let me ask you this.

Here is a company that already has a patent that is workable. The invention was discovered through its own investment.

The company takes a Government contract and in the course of performing that Government contract it makes a new discovery on which its original patent must be the base.

Now, who is entitled rightfully to that new discovery—even though the Government is financing it? The new discovery would be worth nothing without the base—the basic invention, so to speak, that was produced by private investment altogether.

Mr. SHELTON. Well, let me clear up one thing. The mere fact that a contractor has a patent for which itself has paid does not mean that the Government will not acquire rights under that patent if the contractor takes the contract with the Government.

Senator McCLELLAN. What I am trying to do, as I think this thing through as best I can, is this.

Here is a company that has already got a process that it has patented. The Government gives it a contract for something else, but in the course of performing the contract for the Government it discovers a way to improve this original process that it has developed by its own resources and has been using.

suppliers who can choose whether or not to bid on a certain program, and who will forgo responding to a request for proposal or an invitation for bid particularly if there are privately financed programs to protect. If Senator Long's proposals were enacted into law, research and development efforts of a large segment of industry would tend to become compartmentalized into Government and commercial projects for the protection of private rights, and the crossfeeding of ideas between the two would cease. The start of this can already be seen in indsutry today by the formation of Government divisions. If this should become common practice, it would have a seriously adverse effect on the overall Government research and development program and upon the public interest.

On the other hand, the McClellan and Saltonstall bills recognize the need for leaving each Government agency with the authority to give prospective contractors enough of an incentive to engage in Government research and development to attract those who are outstanding in the field because of their own privately established positions. Although these bills establish guidelines for the various agencies, they recognize the old truth that one cannot legislate good judgment and they permit the agencies to deviate from the principle of the guidelines in the presence of special circumstances.

History has many examples of the excellent results which can be achieved when the Government and industry have been permitted to pool their resources in a common effort, neither the contractor nor the Government being forced to give up its rights unjustifiably.

In short, the McClellan and Saltonstall bills take into consideration the very important requirement of the Government agencies, namely, that they offer sufficient incentives to attract industry to enter into contracts on reasonable terms while, at the same time, the interests of the general public are fully protected. The Long bill, on the other hand, in addressing itself to the question of getting the so-called spin-off inventions into commercial use, denies the agencies the flexibility they need to enter into contracts on reasonable terms in order to successfully and expeditiously perform their missions.

While we reject the Long bill, we believe that S. 789 and S. 1809 propose equitable and feasible policies that would largely preserve the incentives of the American patent system and put such incentives to work in the public interest. We could subscribe to the policy of either bill. However, S. 1809 is patterned principally upon the President's Statement on Government Patent Policy dated October 10, 1963, and there is evidence that such a policy will work fairly well. Accordingly, we endorse Senator McClellan's bill, S. 1809, and will not comment specifically on S. 789.

Mr. Chairman, we think that S. 1809 could be improved by modifications which we consider to be relatively minor, and I think I might discuss some of those.

Senator McClellan. Very well.

Mr. Shelton. The bill speaks of the principal or exclusive rights in invention. But it does not attempt to define what is meant by that.

Now, this is true also in the President's patent policy statement, and the administration of that statement results in that expression—the principal or exclusive rights—being interpreted as meaning title.

he happens to make a discovery that would implement or improve it, and has to make it available to the Government.

Mr. SHELTON. Well, if he had completed his invention that he had patented in the sense that he had actually reduced it to practice, them there is nothing in these bills which would say that the Government got any rights under that patent.

But so often——

Senator MCCLELLAN. Not under that original patent—but the new discovery that implements or improves it, which would also be patentable—it would not have a base except for the original invention.

Mr. SHELTON. That is correct.

Senator MCCLELLAN. Who gets the original invention—if the Government gets the new one under its contract, how can the Government use it or anybody else use it unless the contractor has also surrendered his original invention?

Mr. SHELTON. Well, I am trying to explain how the Government can get rights and as a matter of fact title to that original patent. And this would occur in most cases where the research and development work performed by that contractor, and on which his patent is based—if that work had not resulted in an actual reduction to practice. And I mean by that that this work had not been carried on to the point where the contractor had actually built a device embodying that invention and had put it through successful tests which proved that it was operable for its intended purpose.

Now, in that case, if the contractor had not carried the work on that far, if a contractor with this patent took a contract with the Government, with the title clause in it, he would be required to assign that patent to the Government.

Senator MCCLELLAN. Yes, I can see that—I was trying to give an illustration where the patent was already operating, where he had already taken it out and the invention had been perfected so far as making it commercially valuable.

But in performing a Government contract he makes a discovery that makes it even more valuable and improves the original invention. But this discovery also has to be patented. And the original invention is the base.

Now, who gets that original patent? Does the Government acquire that, too?

Mr. SHELTON. No, the Government would not acquire it.

Senator MCCLELLAN. Well, then, that second patent would be valueless if the Government could not use it.

Mr. SHELTON. It would not be valueless after the original patent had expired.

Senator MCCLELLAN. Well, I mean for the period that the contractor was protected under his original patent it would be valueless.

Mr. SHELTON. It would not be valueless if it had utility other than within the scope of the original patent. But if it was just a narrow improvement on a patented invention——

Senator MCCLELLAN. I can understand why a contractor might shy away from a Government contract if the Government wanted research done in a particular field, where the contractor had become somewhat proficient in it—at least had made considerable investment and thought

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Senator Russell B. Long on the one hand, and S. 1809 and S. 789 introduced by Senators McClellan and Saltonstall respectively on the other.

The Long bill is obviously based on the assumption that a policy of the Government taking title to patents will not interfere materially with procurement by the various Government agencies in making the types of contracts which are necessary to enable them to meet their responsibilities in achieving the missions for which they were created. In this day and age when technological progress is so vital to the defense and well-being of the country, this is not only a very dangerous assumption to make, but evidence already before this subcommittee as well as the Committee on Science and Astronautics of the House clearly indicates that such an assumption is wholly unjustified.

The establishment of a rigid Government-take-all patent policy such as Senator Long proposes would tend to make industry shy away from Government contracts.

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Senator McCLELLAN. What I am trying to do, as I think this thing through as best I can, is this.

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try conducts its own business—on the theory that whenever industry goes to another company for a research and development job, it requires that particular company to assign title to inventions and patents to the contracting company. This is not the general practice of industry. I do not mean to say that industry never does this, but the general practice is that it does not require title. And the reason for this is a very simple one.

In the first place, if you contract with a manufacturing company for them to do some research and development work in their field, and you tell that company any inventions that they make have got to be assigned to you, we know that we will pay through the nose for the assignment of those inventions, because that company is just not going to want to assign these, and it is just not worth that much money.

In other words, the main interest of manufacturing companies is the production and sale of goods. It is to further that interest that they perform research and development work and the profits on such efforts are a secondary consideration. To such companies, the right to retain title to any inventions they might make in the performance of a research and development contract is valued very highly, because there is always a chance, no matter how slight, that an important invention having significant value to them in their business will result if they devote their very best efforts to the work. For this reason, industry would have to pay such companies a great deal more for research and development work with title to patents than for such work without title to patents.

Moreover, because the likelihood of any company making inventions of significant value in the performance of R. & D. is totally unpredictable at the time of contracting and occurs relatively infrequently. industry realizes that in contracting for R. & D. with any company to which title to patents is important, it gets much more for its R. & D. dollar, and better contractors too, if it does not demand title to patents.

So I would say that this statement, that the Government is merely trying to negotiate with business on the same basis that business negotiates with itself, is not a correct statement.

Mr. Chairman, I have kind of skipped around. I have not done much reading of this statement. But it is all in the record.

Senator McCLELLAN. Yes. Your statement may be printed in the record in full.

(The prepared statement of Mr. Shelton follows:)

STATEMENT OF THE AEROSPACE INDUSTRIES ASSOCIATION

My name is Charles L. Shelton. I am director, patent section, of the United Aircraft Corp. but appear today representing the Aerospace Industries Association of America, Inc. (AIA). I have served as chairman of the patent committee of the AIA, and presently am the chairman of the Federal patent policy subcommittee of that committee. My statement before the subcommittee is an expression of the position of the Aerospace Industries Association on the matter of a Federal patent policy.

The membership of the association is composed of the principal manufacturers of aircraft, spacecraft, and missiles, as well as their powerplants, guidance systems, and components. Our members are engaged in commercial markets as well as in contracts with many Government agencies and have had long expereice in the field of research and development. Approximately one-

deeply interested in the subject, who have a responsibility in this field, and who are experienced and are capable of giving us counsel.

Thank you very much.

Do you have any questions, Mr. Brennan?

Mr. BRENNAN. Mr. Quigley, are you acquainted with the patent amendment that was offered on the Senate floor last month to S. 596?

Mr. QUIGLEY. Heart, stroke, and cancer—yes, I am generally familiar with it.

Mr. BRENNAN. Did the Department support that amendment? There was some confusion during the Senate debate as to what the position of the Department was. Could you clarify this for the record?

Mr. QUIGLEY. Well, to that end, and I hope I suceed—I think the position of the Department was that if an amendment along those lines was to be adopted, this amendment, as it was sponsored by the Senator from Louisiana, was acceptable to the Department. This was an amendment to an amendment. It was worked out from the original proposal by Seantor Long. We indicated that if the Senate and the House were to adopt a measure along this line, we felt we could live with this in these particular areas of research.

Senator MCCLELLAN. You want to submit that as an amendment to that, or do you want to submit a revised version?

Mr. QUIGLEY. I think a revised version, because I think more appropriately this would go as an amendment to Senator Long's bill rather than as an amendment to the chairman's bill. But I think somewhere in this direction would be the thrust of any amendments we would suggest.

Senator MCCLELLAN. I want everyone to be free to offer their best judgment on this, and be as helpful as possible.

Mr. BRENNAN. Mr. Quigley, do I correctly understand your statement to indicate that the Department's position is that the Department favors a mandatory requirement that you must acquire patent rights in all inventions relating to public health?

Mr. QUIGLEY. No; you are not correct in that, and I think this is where we parted company with the original proposal by Senator Long.

Mr. BRENNAN. So you are not supporting, then, the amendment that was offered on the Senate floor?

Mr. QUIGLEY. I think we indicated that if an amendment was to be adopted to the bill, that in our judgment this was far preferable to the original proposal. I think our issue with Senator Long's proposal has been the mandatory requirement—despite the fact that as a general proposition, as a general policy, in our areas of research, health, and welfare, we think generally this is a good approach—but we think there ought to be enough flexibility within the Administrator to make exceptions in exceptional cases, the Government not taking title—that would best promote the common good.

Mr. BRENNAN. So the Department then would prefer to retain some measure of discretion?

Mr. QUIGLEY. That is correct.

Mr. BRENNAN. Thank you.

Senator MCCLELLAN. All right. Thank you very much. If you will submit the amendments to us here, we will be glad to weigh them.

S. 1809

As stated above, we endorse S. 1809. However, to clarify, strengthen, and facilitate the administration of the bill, we offer the following proposed changes or amendments:

1. In several places S. 1809 refers to the agency head acquiring for the Government "the principal or exclusive rights" in inventions. This same language also appears in the President's statement on Government patent policy, and certain executive departments have construed it as meaning title in every case. We think the bill intends this expression to be broad enough to include title, but not to be limited thereto. Also, we do not believe that the Government really needs to acquire title to a patent in order to fully protect the public interest. To clarify the meaning of this expression and to provide adequate and flexible guidelines for the various Government agencies in promulgating regulations to the end that they will not speak only of title, we suggest that a new paragraph (i) be added to section 2, after line 13 on page 3, reading as follows:

(i) *The term "the principal or exclusive rights" means, but without limitation thereto, either*

1. *title, or*
2. *exclusive license, subject to section 3(b)(3), or*
3. *an undivided part ownership of the patent with the contractor, or*
4. *a nonexclusive license with the right to grant sublicenses, or*
5. *a nonexclusive license with the right to compel the granting of licenses to others on reasonable terms.*

2. Amend section 2(c) by adding after the word "contract" on line 15 of page 2, *which has as a purpose the conduct of experimental, development, or research work.*

This proposed amendment is to conform the first and second sentences of section 2(c); and to conform section 2(c) with section 3(a).

3. Amend section 3(b)(2), lines 6, 7, and 8 of page 4, by deleting "or by a foreign government pursuant to any treaty or other agreement with the Government of the United States."

Because of provisions in current bilateral agreements between the United States and certain foreign countries, the present language of section 3(b)(2) would automatically convey a license to foreign governments under contractor-originated inventions whether or not the United States receives reciprocal rights from contractors to foreign governments. To our knowledge no foreign country has enacted legislation (of the type proposed in S. 1809) to implement article V of the standard bilateral agreement (study No. 24, Patent and Technical Information Agreements, 86th Cong., 2d sess., pursuant to S. Res. 240, 1960). Hence, any foreign citizen who owns a U.S. patent can assert it against the U.S. Government. We believe that either the U.S. Government or the contractor should receive a quid pro quo for such licenses rather than the Government giving them away as would result from the present language of 3(b)(2).

4. Amend section 3(b)(3) by adding after the word "invention" on line 12 of page 4, *together with the right to grant sublicenses thereunder to the extent the contractor was legally obligated to do so at the time the contract was awarded.*

This is merely to permit the contractor to honor his existing legal obligations and is wholly in keeping with the Government's objective of working inventions.

5. Amend section 3(b)(8) by inserting after the word "knowingly" on line 12 of page 6, *and with intent to defraud the Government.*

We agree that if a contractor deliberately and for the purpose of defrauding the Government withholds a disclosure, there should be a penalty. Our concern here is that the present language could be construed broadly enough to punish an honest error or a mistake of judgment.

6. Amend section 8(b) by inserting after the word "head" on line 3 of page 15, *shall make all patents acquired under this Act on behalf of the United States freely available to the general public of this country and, in addition* * * *

In lines 3, 4, 5, and 6 strike "an exclusive * * * of the United States" and substitute, *licenses to others under any such patents.*

The foregoing changes to section 8(b) would make this bill consistent with our views expressed below on the subject of the Government having title to patents.

Unfortunately some patented inventions, particularly those requiring a substantial investment to adopt them for public use, may not reach the commercial

to question seriously whether the advantages of consistency which such a centralized arrangement might provide would not be outweighed by the disadvantages. Of perhaps even more serious import are the provisions of section 7(a) which would make the Federal Inventions Administration the agency principally responsible for the receipt, storage, and dissemination of scientific and technical information deriving from research and development activities of Federal agencies and their grantees and contractors. There already exist organizations responsible for the collection and dissemination of technical information, for example, the Science Information Exchange, the Clearinghouse for Federal Scientific and Technical Information, and the National Library of Medicine. Apart from the question of the duplication of such resources and repositories of information, there is raised the question whether the provisions of the measure would result in an undesirable diversion of scientific and technical information away from traditional sources.

Section 7(b)(2) provides for the evaluation of scientific technical information available to the administration to determine its probable application to commercial uses in the development of new and better products and advanced technological methods of production. For one Government agency to assume the monumental undertaking of evaluating the results of all research as to their suitability for commercial uses, a task which is now performed on an ad hoc basis by industry and the entire scientific community, would be prohibitive in terms of appropriations and the manpower needed to perform such a task.

In summary, Mr. Chairman, we believe that further experience under the existing policies laid down in the President's statement is desirable. However, if comprehensive legislation is to be enacted at this time the chairman's bill, S. 1809, would in our opinion be the appropriate vehicle if amended along the lines suggested in our report.

This, Mr. Chairman, concludes my summary, and I shall be glad to answer such questions as you may have.

Senator McClellan. Thank you very much for your statement.

If I understand, you sum up your presentation by saying you do not think any legislation should be enacted right now, that we should wait for further experience under the President's directive.

Mr. Quigley. In essence, Mr. Chairman, this is our position.

Senator McClellan. That is No. 1. And No. 2—if a bill is to be passed, you think S. 1809 offers the best vehicle at this time, and you would recommend it only, though, if it is amended.

Mr. Quigley. That is correct, Mr. Chairman.

Senator McClellan. Along the lines of your suggestions.

Mr. Quigley. Of the three bills before the committee, we would endorse—come closest to endorsing S. 1809 because we think it comes closest to the President's statement of October 1963. We would like to bring it even closer to that.

Senator McClellan. Well, not just because it may conform to some Presidential directive—but it is the merit of it we want. What we are seeking here is what legislation is best.

While it may come nearer to conforming to the President's directive than the other bills—unless you wholeheartedly support the directive and think it provides the solution and the best policy—if so then all we need to do is adopt the Presidential directive.

ment, which will make the invention freely available to all for commercial as well as governmental purposes. If A does not take the contract, its exclusive commercial position will be preserved and the existence of the patent may enhance its chances of getting a production contract from the Government after B has developed the item under the Government research and development contract. In any event, A can recover just compensation from the Government for B's work and also if the Government production contract goes to another. In this type of situation the policy of the Long bill would definitely discourage the qualified company from taking the contract, but the inexperienced and less qualified company would find it less objectionable.

The philosophy implicit in S. 1899 that the incentives of the U.S. patent system should be excluded from Government contracts should and must be rejected.

S. 1047

This subcommittee is also considering S. 1047, introduced by Senator Williams, to amend section 1498 of title 28, United States Code.

The AIA presently opposes any basic change in the principles of section 1498, and therefore cannot support S. 1047. However, we do favor legislation giving patent claimants easier access to the courts in pursuing claims against the United States. For example, a patent claimant could be permitted to bring such in his "home" district, or circuit, or the Court of Claims system could be enlarged to permit trial before a commissioner in the claimant's "home" district.

The Aerospace Industries Association appreciates the opportunity to present its views and, as in the past, stands ready to offer any assistance deemed necessary or desirable by this subcommittee.

Mr. SHELTON. If there are any questions, I would be happy to try to answer them.

Senator MCCLELLAN. Well, I have asked you the principal one.

I had requested the other witnesses who preceded you to submit the proposed amendments, and I see that you have done that in your prepared statement.

Mr. SHELTON. Yes, sir.

Senator MCCLELLAN. These are the amendments here that you would recommend.

Mr. SHELTON. Yes, sir.

Senator MCCLELLAN. And you spell them out and have prepared them in the language you think appropriate.

Mr. SHELTON. That is correct, sir.

Senator MCCLELLAN. Very good. Thank you very much.

Senator Scott, any questions?

Senator SCOTT. No questions.

Senator MCCLELLAN. Well, thank you, sir.

Mr. SHELTON. Thank you.

Senator MCCLELLAN. Mr. Quigley, will you come around again, please.

STATEMENT OF JAMES M. QUIGLEY, ASSISTANT SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY MANUEL B. HILLER—Resumed

Senator SCOTT. I appreciate your standing by to enable me to get back.

I had a few questions I wanted to ask.

I understand from time to time the NIH grantees have invented new chemical compounds having a potential value as a new drug. That is right; is it not?

of rights to the results of such research, and a summary of our recommendations concerning the three measures under consideration by this committee.

As you are aware, constituent agencies of the Department engage in and support research in the life sciences, social sciences, and the physical sciences.

The major portion of our research is medical research and is carried out through the grant mechanism rather than through contract. Also, a very considerable amount of medical research is carried out intramurally in such facilities as the National Institutes of Health, our Communicable Disease Centers at Savannah and Atlanta, Ga., and the Taft Sanitary Engineering Center at Cincinnati, Ohio. The total research budget of the Department for fiscal year 1965 totaled $735 million.

Consistent with the Department's statutory responsibility for the advancement of secience and knowledge and the dissemination to the public of the results of research, it is the general policy of the Department that the results of Department-financed research should be made widely, promptly, and freely available to other research workers and the public, by publication and by royalty-free licensing under protective patents or by dedication of Government-owned inventions, though our regulations permit of some exceptions to this where the public interest in achieving the development and practical application of inventions can best be promoted through other means. I might add, in this connection, that our regulations on this subject have been and are under intensive review within the Department to assure that they are effective to accomplish the wide, prompt, and free availability of scientific advances to all segments of the public.

In this context, we regard the provisions of S. 789 now before this committee as wholly incompatible with the Department's research objectives and our current policies and practices. The basic premise of the bill, that the Government should normally acquire only a nonexclusive license for governmental purposes whereas the contractor or grantee shall acquire ownership, is at odds with our concept that the taxpayer is entitled to the fruits of research financed by tax funds. Those provisions contained in the bill under which the Government might acquire more than such a license would not generally be applicable to situations in which our Department is likely to be involved. Moreover, the procedural requirements incident to governmental acquisition of greater rights are so cumbersome as to render illusory the opportunity of the Government to acquire more than a license. We are, therefore, opposed to the bill and urge that it not be favorably considered.

S. 1809, on the other hand, reflects, in the main, the criteria set forth in the Presidential statement on Government patent policy issued in October 1963. Insofar as it would apply to our research activities, the bill embodies the principle that, in general, the Government should acquire rights to inventions resulting from Government-financed research for the benefit of all the people and, of course, we firmly endorse that policy. However, even apart from certain departures in the bill from the criteria contained in the President's statement, we believe that more experience under the statement is

PHS grant (one of five sources of support), was assigned to the University of California under its agreement with the Public Health Service in order that it may issue an exclusive license for development of the invention. It issued an exclusive license for 5 years to Lederle Corp. This invention was covered by 10 patent applications under which a license was executed to the Government in 1958. The university subsequently assigned all of its rights to the inventor, Dr. Penn, which assignment, in the opinion of the Public Health Service, was in violation of its 1953 agreement with the university and it institutional agreement which postdated the 8.2(b) determination by 2 years (institutional agreement was entered into March 21, 1955). After considerable correspondence it was determined that one application was still pending in 1962. The University of California subsequently admitted its error in abandoning to the inventor these inventions which they considered worthless. Since the inventor had left the country and was then in India, there was little that could be done to rectify the error. Dr. Penn had licensed the California Corp. for Biochemical Research on an exclusive basis for the life of the patent. There is no information in our file with regard to either the commercial development, if any, of the drug, or its effectiveness.

2. On September 26, 1955, an invention "Low Noise Amplifiers for Use in X-Ray Screen Intensifiers of the Television Type System for the Translation of Intelligence at Low Signal to Noise Ratios" was made at Johns Hopkins University, with some support from a PHS grant, by Dr. Russel H. Morgan and Ralph E. Sturm. The circumstances in this case were unique:

(1) The inventors had been working on this invention over a long period of time while pursuing graduate and postgraduate work, contributing much of their own funds prior to PHS support.

(2) Although sizable contributions were also made by the university, the university did not wish to administer the invention and felt that equity called for assignment to the inventors.

(3) Patenting and exclusivity were necessary to bring this complex scientific discovery to the market. Attempts to interest several commercial organizations in marketing this invention, useful in hospitals and other medical agencies, were unsuccessful.

(4) Additional expensive developmental work was required on this complex electronic device which would be undertaken only by someone assured of long-term exclusivity.

A determination was made by the Surgeon General on September 26, 1955, and amended on November 18, 1955, permitting the inventors to retain rights to the invention covered by two patent applications and to sell or license the patent applications to a commercial corporation which in this case was Bendix Aviation Corp., subject to conditions that may be imposed by the Department of Health, Education, and Welfare. The Government reserved a license (nonexclusive, irrevocable, and royalty-free for all governmental purposes). It approved the agreement between the Bendix Corp. and the inventors which included amount of royalties to be charged. The Government required that Bendix Aviation Corp., after 10 years from April 5, 1955, make the invention available through nonexclusive licensing of other manufacturers in the fields of medicine and public health, the royalties not to exceed 5 percent. Bendix agreed to give priority to development in these fields. If, after development of the invention to the point of utility and satisfactory quality, Bendix could not meet the demand, in any field, it would be required to nonexclusively license other qualified manufacturers at royalties not to exceed 5 percent. No royalties were to be included in the price of any sales to the Government by Bendix or by any assignee or licensee.

3. On September 8, 1959, a determination was made to assign an invention entitled "Air Pollution Testing Instrument for Measuring Pollution in Gases" invented by Addams, Koppe, and Dana under an air pollution contract with Washington State University to the contractor for development and administration. It was proposed that the college would give a 5-year exclusive license to an interested, reliable manufacturer under terms which "would insure the continued and rapid production of a satisfactory product). At the termination of the 5-year period licenses would be "available to all manufacturers on a nonexclusive royalty licensing basis." Subsequently, the college concluded that patenting would be uneconomical and the invention became unpatentable as a result of its prior publication. A supplemental determination was written reflecting the situation.

impose its requirements on top of the work that has already been done at the private expense of the particular contractor. The contract might be for a very small amount. And if he were to give up his commercial rights for a very small consideration he would, I am sure, think twice about it, and his board of directors would be quite concerned about that situation, too. But in your example, I do not think that there would be any doubt but that the best talents would be applied to the job.

Senator BURDICK. I do not think that any segment of American business enters into a contract, let us say, at the cost of 7 percent that would not do its best in such a situation.

Mr. MALLOY. I would hesitate to say that they would not do their best, because I do not know that this can be proved one way or the other. But in that situation a particular contractor, for the reasons we have stated, may not want to enter into the contract with us in the first place. I think that if he did, I would, certainly, not want to say that he would do less than his best, except in those situations in which human nature might take a hand and the incentive would be against the application of the best ideas.

Senator BURDICK. A transaction for research and development in a contract is at an agreed upon figure, ordinarily?

Mr. MALLOY. Yes.

Senator BURDICK. That is an incentive in itself, is it not?

Mr. MALLOY. What is that?

Senator BURDICK. That is a piece of business in itself?

Mr. MALLOY. It certainly is.

Senator BURDICK. Which most American business would honor and perform?

Mr. MALLOY. Yes, sir; that is right.

Senator BURDICK. Do you know of any instances in the Defense Department where a contractor has refused to enter into a contract, where he was denied patent rights?

Mr. MALLOY. No, sir; I know of no such instance. I suppose that in our experience that has been true more because we have not had in the past a policy of taking title. We have left title to inventions with contractors and have not really had the problem, so that we are looking ahead really and speculating as to what might happen if there is a radical change in the patent policy.

Senator BURDICK. That is a speculation. But according to history and facts there has not been anybody who has refused to do the work?

Mr. MALLOY. I know of none, Senator Burdick. I suppose that there might be some, but as a generality this has not been a problem in the past with the Department.

Senator BURDICK. Well then, the closing question, then you think that the taxpayers in this work—it is just that simple, is it not—would not lose?

Mr. MALLOY. Senator Burdick, I think that, as with all of the questions that are before us in this consideration of patents, it tends to be an oversimplification. I think that this is the easiest thing to do in this field. I think that is, possibly, one, because as I indicated before, it stands on certain presumptions that are not necessarily true.

Senator BURDICK. What is the answer to my question then?

private foundation, in which case it would be unfair and inequitable for the Surgeon General to exercise the Government's right.

Senator SCOTT. That would indicate, then, that HEW believes these other groups, if they help to finance the cost of an invention, would have the right to share in the patent.

Mr. QUIGLEY. Very definitely, Senator. This is not on policy now, but as I indicated, our regulations in this area are under review.

Senator SCOTT. Do you have any information, even roughly, as to how many NIH grantees also receive financial support from non-Government sources?

Mr. QUIGLEY. I do not know that we have any such figures. If we have, we would be happy to supply it for the record.

In my own judgment, I think it would be a substantial number, because I think some of the better researchers are likely to attract support from a variety of sources.

(The information referred to follows:)

We have tabulated the information reported in question 6–B–1 of the Public Health Service application form 398 from the 3,467 applications reviewed by study sections in the June cycle. Two exclusions were made: support from the "own institution" of the investigator and support from Federal agencies. The data, therefore, reflect the proportion of investigators who have research support from others and than his own employing institution or the Federal Government.

Principal investigators with "outside" support

Number of "other" sources	Principal investigators	
	Number	Percent
0	2,650	76.7
1	603	17.4
2	142	4.1
3 or more	63	1.8
Total	3,467	100.0

Senator SCOTT. Now, I understand that NIH in the grant application that each investigator must fill out asks for detail and specific information—"All other research support." The investigator is asked to state the title of his research project, the amount, and the amount of time he is spending on the project. Now, this is question 6–B on the grant application.

If you have been obtaining this information from all the NIH grantees, could you not run this information through one of the Department's computers and give us an answer to that?

Mr. QUIGLEY. Probably we could. Offhand I know of no reason why we could not.

Senator SCOTT. I do not know much about computers, but I am prepared to assume they can do almost anything.

Mr. QUIGLEY. I think we will move forward on that assumption. If we prove to be wrong, we will be back to say it could not be done, for whatever reason.

Senator SCOTT. I think it would be helpful—to determine the extent of multiple sponsorship of research in the medical field, measure

research work. Company B has had years of experience in this particular area—has not quite succeeded in getting a breakthrough. And so they enter into that contract for a consideration. And they do develop something. They do make a finding. Is it true in the commercial world that company A obtains all of the patent rights?

Mr. MALLOY. It is not nearly as clear as to what is the normal practice between two commercial concerns in the situation you have described. It is my understanding, actually, that the more usual practice would be that company A would not ask and not receive title to inventions discovered in the performance of this contract. This is by no means an across-the-board type of conclusion.

We made a survey some years ago, I believe it was for the Senate Small Business Committee, and found that the practices of the Department of Defense contractors were pretty generally against taking title to patents in your situation, but that there were some exceptions. Where company A was intimately involved itself in the development of the particular item, had invested a lot of its own know-how and money, then it might ask for title in those circumstances.

So to sum up the generality, as I undertsand it, in commercial transactions, the company placing the research contract does not request or get title to the patents that are developed by the other concern. This is because commercial companies are not normally in the business of inventing for other companies. The exception, I guess, to this would be companies that are in strictly research business—they are in the business of making their talents available to other corporations and have no objections whatsoever to giving up titles to any inventions, primarily because they are not in the business of exploiting them.

Senator BURDICK. Maybe I did not make myself clear. This is a case where company A hires or contracts with company B to do research work for company A.

Mr. MALLOY. Right.

Senator BURDICK. They pay them under the contract. Is it your testimony that company A does not retain the patent rights?

Mr. MALLOY. Not normally.

Senator BURDICK. Not normally?

Mr. MALLOY. Yes, sir.

Senator BURDICK. That is news. There has been testimony to the contrary.

All right, you testified here a few minutes ago that under S. 1899, the public interest would suffer most, because there is not a proper balance. Is that what you said? If S. 1899 were adopted and all patent rights went to the Government, you said that the public would suffer most because it was not a proper balance of equity. Let me call your attention to page 21, line 20—you have a copy of S. 1899 before you?

Mr. MALLOY. Yes, sir.

Senator BURDICK. Let me read it to you:

Under such regulations in conformity with the provisions of this section as the Administrator shall prescribe, he may waive all or any part of the proprietary rights of the United States under this act with respect to any invention which has been made by any person or class of persons in the performance of any

Mr. QUIGLEY. And I think rightly so. It does not strike me as the fair thing to do. As I say, it does not particularly involve our Department and its mode of operating.

Senator SCOTT. You and I have been engaged in many perilous operations over the years, and I want to thank you very much, Mr. Secretary.

Mr. QUIGLEY. Thank you, Senator. We will supply for the record the information you have requested. If for some reason or other we cannot run the 18,000-some grant applications through the computer and come up with that answer, we will report that fact to you.

Senator SCOTT. All right. Thank you. And thank you, Mr. Chairman.

Senator MCCLELLAN. All right. Thank you very kindly. Our next witness is Mr. Morton. Mr. Morton, you may identify yourself, please, sir.

Your statement will be printed in the record and you may highlight it if you wish. You represent the American Patent Law Association?

STATEMENT OF W. BROWN MORTON, JR., PRESIDENT, AMERICAN PATENT LAW ASSOCIATION

Mr. MORTON. Yes, Mr. Chairman, I am president of the American Patent Law Association at the present time.

Senator MCCLELLAN. Very good.

Mr. MORTON. I have over the years devoted some attention to this subject. I have reviewed the statement. It correctly expresses the long-considered policy of the association.

I am pleased to see that it meets the chairman's suggestion of specific suggestions for amendment to the bill. It has specific suggestions embodied in it, Mr. Chairman, for language changes in S. 1809 already in the statement.

Senator MCCLELLAN. Very well.

Mr. MORTON. I think to highlight our position I will refer to what the statement says on page 3 in the next to the last paragraph.

It seems to us that a great deal of the discussion of this subject has turned on whether the Government gets what it pays for. It obviously is entitled to get what it pays for. It seems to us the Government, by the policy personified by the Long bill, and various Long amendments to specific instances of Government research legislation, is insisting on getting more than what it pays for. Perhaps that is what Senator Scott has in mind with the reference to fallout inventions.

Let me give you an example, if I may, that has occurred to me of what I have in mind.

Let us suppose that the Government wants a radio set specially designed to function well under the damp conditions of the jungles of Vietnam. It applies to a contractor to jungleize a radio. The contractor puts his best men on it. Under the criteria laid down ordinarily in these Long bills, for lack of a more generic term, the contractor, if the invention is made during the course of the work done on the contract—has to turn over title to the Government.

Senator MCCLELLAN. Now, the fallout, so to speak.

This is another thing that you cannot prove with great mathematical precision, but this has been of great concern to the Department for many years and the officials of the Department have this concern today.

Senator McCLELLAN. Who suffers under these the most, the Government's interest, or the public's interest or the contractor's interest, if S. 1899 is adopted—which suffers the most?

Mr. MALLOY. Whose interest would suffer the most?

Senator McCLELLAN. Under the provision, the Government takes title to all and where the Government takes it in the interest of the public, primarily, because that is the only reason for the Government's taking title, because public funds have paid for the research, No. 1—No. 2, the Government, even where the patent rights remained in the contractor, the Government takes a license for its purpose—so it is the public interest, and the contractor's interest, the private enterprise system interest that is involved. Now, which would suffer the most, ultimately, under the provisions of S. 1899, if we enacted that into law?

Mr. MALLOY. Mr. Chairman, it would be my view that the Government's interest would suffer the most, and for the reasons that I just indicated, that we would, probably, not be able to get our research program handled by the very best research contractors.

Now it is also, of course, true that a contractor would lose an advantage as well if the Government had title, but the contractor would not necessarily have to place himself in that position. He could avoid the problem by avoiding the contract.

Senator McCLELLAN. I think that what we have tried to do here, with due diligence to our free enterprise system which we do not want to destroy or unduly or unnecessarily impair—where the Government spends money, the public interest becomes involved—it is public funds that are being expended—so that I think that in trying to resolve a delicate and complex issue such as has arisen here, it would be well for us to consider not just the initial equities and advantages that one may get or the other may get, but what is going to be the long-run, overall impact upon the public interest and upon the free enterprise system, and your conclusion is that, ultimately, the public interest would suffer the most?

Mr. MALLOY. Yes, sir, Mr. Chairman.

Senator McCLELLAN. Precisely and concisely as you can, please state why.

Mr. MALLOY. The President's policy tries to weigh this delicate balance and come up with a solution. The issues that were involved were first, how to get the best performance under Government research and development contracts, and, second, how to get the most benefit for the public from the fallout benefits that result from the spending of Government money on research and development. Our feeling—I know that it is the thinking behind the President's policy as well—is that we are able to get the best research and we are able to bring to the public, through the incentive provided by the patent itself, these spinoff benefits better by leaving title to the commercial application with the contractor.

governmental purpose. But we see a fundamental distinction which we feel has been overlooked by many people in this field between acquiring an invention and acquiring and exercising the exclusive rights in a patent on an invention.

Now, generally speaking, Government research is not and should not be intended to produce inventions having commercial application. It is intended to produce inventions, largely inventions which would not be made except for Government intervention—that is, they are threshold inventions, or to use a term——

Senator McCLELLAN. Well, that would be true as in the Defense Department, possibly. But that would not be true in the medical field, would it?

Mr. MORTON. If I may say, I think it would, sir. It seems to me that in the field, for example, of improved bandages, we can relax and let the commercial enterprises take care of that. In the field of a cancer cure, where breakthrough inventions are necessary, no doubt Government funds are justly expended.

Senator McCLELLAN. We have a rollcall vote. Do you have more that you wish to tell us?

Mr. MORTON. Only this. We feel that the compulsory license aspects of the revisions we have suggested in S. 1809 could well be analogized to the military draft.

It is noticeable, I am sure, to the Senate as well as to the rest of us, that the existence of the draft tremendously promotes volunteering. We think that the existence of the compulsory license prvoisions, even though they seem a little rigid in their application, will largely eliminate the necessity of proceedings under them, that there will be a free exploitation of inventions made by virtue of the adoption of these provisions without the necessity of going through all that litigation.

Senator McCLELLAN. Thank you very much.

(The prepared statement of Mr. Morton follows:)

STATEMENT ON BEHALF OF THE AMERICAN PATENT LAW ASSOCIATION

The position of the American Patent Law Association with respect to Government patent policy is set forth in the following resolution adopted by the board of managers of the association in the spring of 1964:

"Whereas it is the position of the American Patent Law Association that progress of the useful arts is best promoted when inventors are made secure 'in the exclusive right to their * * * discoveries,' because the protection of such exclusive rights affords a vital incentive to private enterprise to assume the economic risks involved in developing new products, in introducing them to the public, and in promoting their use; and

"Whereas it is the conviction of the American Patent Law Association that Government authority cannot and should not undertake the introduction and exploitation of new products in the public marketplace in competition with private enterprise;

"Whereas the American Patent Law Association is duly appreciative of the positive steps taken during 1963 to solve the complex problems leading to a uniform Government patent policy as embodied in the President's statement of Government patent policy (of October 10, 1963), the McClellan bill, S. 1290, the Saltonstall bill, S. 1623, the Toll bill, H.R. 4482, and the Daddario bill, H.R. 471, and has made an intensive study of the statement and the several legislative proposals: now, therefore, be it

"*Resolved*, That it is the policy of this association that where the Government of the United States seeks to avail itself of the skill, resourcefulness, and creative ability of private enterprise, and enters into research and develop-

In most other situations, the President's policy calls for the Government to take a license at the time of awarding the contract.

Senator McCLELLAN. Particularly, in the field of medicine, if the Government contracts with a university or with some institution, a nonprofit institution, to do research work, certainly, in my judgment, as I view the situation now, the Government should take title.

Mr. MALLOY. That is now the normal situation.

Senator McCLELLAN. And it does that now?

Mr. MALLOY. Yes, sir.

Senator McCLELLAN. Now, suppose that the Government, let us say, writes a comparable contract, let us say, to some chemical company, to do research within a given field, such as cancer, heart, or a similar disease, trying to find a remedy—who should have the patent rights in that contract?

Mr. MALLOY. In that situation, Mr. Chairman, the President's policy calls for the Government to take the title.

Senator McCLELLAN. That is, the title to what the Government is seeking? If they found a remedy, let us say, in the medicine that was useful for that given purpose, very well. But suppose an extraneous finding is made, something wholly unrelated in doing the research for cancer—suppose they found some medicine in that process that cured some other disease, something wholly unrelated to the general objective—to whom should that patent go then?

Mr. MALLOY. It is my understanding, Mr. Chairman, that in that situation title would, also, be with the Government.

Mr. JOHNSON. May I amplify that answer a little bit?

Senator McCLELLAN. Maybe we ought to ask the Department of Health, Education, and Welfare about it.

Mr. MALLOY. I think that is more in their area. The Department of Defense has some contacts in this area but it is a very small part of our business.

Senator McCLELLAN. Go ahead.

Mr. JOHNSON. There may be some cases in which the contract was not intended for a public health purpose. However, in the course of performance an invention is made which proves to have application directly in the health field. In that case, under the President's policy, the Government would have acquired a license sufficiently broad to permit the use of that invention, if necessary to fulfill health needs. In other words, if you were to have a cancer cure developed under a petroleum contract it would be possible to have a license to permit that cancer cure to be made available as rapidly as possible. That is spelled out in the President's patent policy.

Senator McCLELLAN. Another item, you oppose the Government making a renegotiation of a patent right, I believe. You expressed opposition to that. You do not think that the Government should have the right to do this?

Mr. MALLOY. Not in the terms that are included in S. 1809, Mr. Chairman. We think that the bill goes too far. There are provisions in the President's policy which we think amply protect the Government's needs. There are the so-called march-in rights whereby we can, even though we have contracted to leave title to the patent with the contractor, we can come back later and require compulsory licensing

"(B) The contractor has refused to license complainant on reasonable terms; and

"(C) Complainant is able to and will exploit the invention if a license is granted."

The clause we have suggested eliminates the necessity for administrative policing of all patents evolving from the R. & D. funds of each agency which would be time consuming and expensive. However, it does insure that a competent individual or firm can obtain a license if the contractor fails to exploit commercially inventions covered by such patents.

As a practical matter, the inclusion of the statement required by section 3(b)(7) will put private parties on notice as to the availability of a license if the patent owner does not exploit the invention, thus putting pressure on the patent owner to exploit the invention to prevent the issuance of a compulsory license.

Section 4(a) is also approved in principle, but the particular wording contains ambiguities which should be cleared up before the bill is enacted. It is suggested that the following language be used:

"Section 4(a). The agency head may require, at the time of entering the contract, that he be given the right to acquire, on behalf of the United States, an interest greater than the nonexclusive license specified in section 3(b)(2) in inventions if—

"(1) The purpose of the contract is to produce one or more end items, the use of which is or will be required by law or governmental regulation in furtherance of the public health, or safety, and the invention covers such an end item; or

"(2) The purpose of the contract is for the contractor to operate a Government-owned research or production facility, and the invention is especially adapted for use in that facility or in a related facility; or

"(3) The purpose of the contract is research, developmental, or experimental activity in a field of science or technology in which the Government is the sole developer or has provided substantially all the funds for research, developmental, or experimental activity in such field, and the invention is especially adapted for use in such field; or

"(4) The purpose of the contract is research, developmental, or experimental activity in a field of science or technology that is new, without any significant commercial or private history, and probably would not have been developed in the foreseeable future without Government financing, and the invention is useful only in such field.

"(b) Whenever the provisions of section 4(a) indicate that the agency head may acquire an interest greater than the nonexclusive license specified in section 3(b)(2), he shall acquire such greater interest unless he determines, after examination of the facts of the particular case, that special circumstances indicate that the contractor should retain rights in the invention greater than the nonexclusive license specified in section 4(c), including rights in foreign patents, subject to the interest reserved to the United States in section 3(b)(2), and that the public interest would not suffer as a result of the contractor retaining such greater rights."

There are several minor differences in wording in the foregoing and two changes of some importance. In section 4(a)(1) the reference to "commercial use by the public" has been deleted since it is believed that that term is so broad and comprehensive that it could be construed to cover substantially all inventions, a result obviously not intended by the Presidential memorandum in which the language first appeared.

In addition the phrase in section 4(a)(3) referring to the acquisition of exclusive rights has been deleted as superfluous.

A new paragraph 4(b) has been added more clearly to delineate the procedure under the unnumbered paragraph appearing in section (4) of S. 1809 immediately after paragraph (a)(4).

Section (4)(b) is approved without change.

Section (4)(c) is not endorsed by APLA. In view of the preceding language in sections 3 and 4, it is believed that all the parameters involving patent rights are so clearly delineated that section (4)(c) is superfluous. It can have two bad effects: first, to provide an easy way to avoid making a determination under section (4)(a) and (4)(b); second, to increase the ultimate burden on the Gov-

the rights to the patents which result from it without waiting to determine it later."

That question has been raised. Under what circumstances and why should we do that in the beginning, give away the patent? Why not wait until after the discovery had been made, and then settle the proposition?

The case that I gave you is an instant where, possibly, you would grant the exclusive right to the contractor at the beginning, is that correct?

Mr. MALLOY. Yes, sir.

Senator MCCLELLAN. And now one thing further that I can foresee, if the contractor is not to get it, and the Government has a policy where it will take all the discoveries and inventions, have exclusive title to them, there would be a disposition, I would think, on the part of the contractors as you said earlier, maybe not to put their best talents on this particular contract. And, secondly, maybe not to report discoveries made that were not apparent, in other words, let us take the side discoveries, that is, things that were discovered that you were not looking for, that were not necessarily pertinent to the contract, the product that is involved—they would not report those. But they would be required, I assume, under a Government ownership policy to report all of that, and the Government would become the owner of that, too. I can foresee that there might not be an enthusiastic inclination to report all those that were discovered.

Mr. MALLOY. I think both points are well taken. I think that there would be a reverse incentive against reporting in the other situation. It would be against the contractor's interest. Obviously, he would comply with the terms of his contract which requires reporting, but here again is an area of subjective judgment. In a borderline case, in which reasonable men might disagree, these things may not be reported, as you suggested.

Senator MCCLELLAN. How will this affect small business? You made some reference to that. If the Government policy is that of taking title to all patents, how will that affect small business, particularly with respect to incentives? Is an incentive a big factor in inducing small business to bid or to contract to work for the Government?

Mr. MALLOY. Yes, sir. I think that the small contractor needs the type of protection that we are talking about more than the larger contractor. Small contractors very often are the more inventive group, as a group, and the forces of economic competition are tougher on them. The protection afforded by the patent laws is even more important, I think, in this instance, than for the big contractor.

Senator MCCLELLAN. Well now, let us take another instance here where there is an extraneous discovery, something apart from the general objective of the contract involved in the situation that may have no particular use so far as the objective that the Government was seeking in financing it. If that is left in the contractor, if it has a commercial value, the contractor would naturally develop it, of course, but if it does have that commercial value and the Government takes title to it, then, as I understand the rigid policy of Government ownership of these things, the Government simply then makes it available to

You will recall that in my oral testimony I stressed the importance of distinguishing at all times between the situations in which the Government could plainly justify taking title to an invention, including taking title to any patent rights covering, or potentially covering, the invention and the actual ownership and exercise by the Government of right to exclude others stemming from those patents. I had pointed out that certainly it could not be contended that an invention or any rights thereto were immune from the operation of eminent domain, any more than a man's farm is, but I stressed that it was an essential of our political and social system that the exercise of eminent domain be for truly governmental purposes and not simply a strong-arm method of setting the Government up in a commercial enterprise.

Certainly if the National Institutes of Health, for example, were to contract for research intended to produce a cancer cure, it might logically require the dedication of the invention of such a cure, if made during that research, to the free use of the public. Let us suppose that the state of the art, as it may, leads one to surmise that cancer is the result of some virus action. Let us suppose further that one or two of our drug companies have, with respect of virus regulating drugs in other than cancer-producing areas, a substantial background of past experience and patents. Certainly it would be good sense for NIH to spend its research dollars, in part at least, in support of cancer virus investigations, in these well-staffed and well-prepared virus laboratories. Does it follow that all inventions may flow from that research in the areas of non-cancer-causing virus control, which are incidentally made, should also be dedicated to the public because the laboratories had received unquestioned assistance from NIH? I think clearly not.

Now to come directly to the point, let us suppose that because of NIH policy insisting upon such rights beyond the cancer program, these drug companies refused the NIH money but nevertheless, in the course of their normal work, a "windfall" invention is made, with all private funds, of a cancer cure.

If the expenditure of NIH funds for the discovery and public dedication of a cancer cure was justified as a proper governmental activity, does it not necessarily follow that the Government would be justified in taking over the privately invented cancer cure under the power of eminent domain, paying, of course, just compensation therefor? Would anyone assert that although the cancer cure might properly be taken from private hands, that the Government had any justification for taking ordinary inventions made simultaneously in the private program which resulted in the cancer cure?

We come back, therefore, to the situation that, as the association has repeatedly said, the patent system is premised upon the proposition that it affords the best means of promoting the progress of the useful arts in a private economy, just as does the private ownership of farms best promote agriculture in such an economy. Arguments which truly relate to the propriety of Government acquisition of private property by eminent domain do not belong in, and should not confuse the development of, a sound policy and we believe a private patent policy for procuring the exploitation of inventions arising in Government research in the commercial area.

I have taken the liberty of sending a copy of this letter directly to Senator Scott in view of the interest he exhibited at the hearing.

Respectfully,

W. BROWN MORTON, Jr., *President.*

Senator MCCLELLAN. The committee will recess until 9:30 in the morning.

We hope to conclude with what we have scheduled before noon. If we can get through 30 or 40 minutes before noon, that much the better.

(Whereupon, at 3:20 p.m. the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, July 7, 1965.)

Suddenly, the Government needs this product, and so, realizing that this company has done considerable work already, goes to the company and says, "Here now, we have to have this as soon as possible—we need it. We are willing to give you a contract. You put your best men on it and get this thing done, get the breakthrough as quickly as you can."

And the company responds. Where are the equities? Who should get the patent rights on that patent when it breaks through and is accomplished? There is the difficult problem that we have. If you are starting from scratch, so to speak, and you make a contract to develop it and you secure the skills to do the research, certainly the Government would have it. But where the company has already made considerable investment, it goes out and employs people, mobilizes a lot of skills and talents, and it has developed those talents, as well as bringing them into a position where they are competent to pursue the objective—they have an investment in that, and the Government comes along and says, "Well, we are interested in this, too, so we will finance a crash program here, so to speak. We are very much interested. We will give you a contract for certain aspects of this. And we will furnish all the money from here on in."

There are some equities there on both sides. How are we going to distribute that equity?

Mr. MALLOY. Mr. Chairman, we feel that the equity in that situation would lead a prudent man to leave the title to the patent with the contractor. He has assembled some valuable assets, including both physical and human assets and prior research, so that he, obviously, has an investment in the situation. The Government obtains all that it requires when it gets a royalty-free license, to use or to have others use the inventions that might flow from the research work.

Senator MCCLELLAN. The Government has an inclusive right always.

Mr. MALLOY. I beg your pardon?

Senator MCCLELLAN. The Government would get a license for its purposes, in any event.

Mr. MALLOY. Yes, sir. It is a nonexclusive license, so that the Government can practice any invention or have any other contractor practice any invention for Government purposes anywhere throughout the world. So the Government gets everything it needs to get on with its business. We feel that the equities of the situation call for leaving title to the commercial application of the patent with the contractor. We think, also, that this carries out another primary and fundamental purpose, of the President's policy; namely, to get the invention working in the commercial marketplace. If the contractor has a degree of exclusiveness for a period of time, as provided for under the patent laws, it provides him with the incentive to actually bring the invention to the marketplace to make it available to everybody.

Senator MCCLELLAN. That is giving the patent away. If you give it to the contractor, the exclusive rights, subject to Government license to use it, that is giving away something. That is the way I interpret this. Woud you so interpret it?

Mr. MALLOY. Mr. Chairman, that gets to be a kind of a broad generalization.

Dr. PRICE. I would like to start by mentioning that our society was founded in 1876, and it is the largest membership organization devoted to a single science in the entire world. It now operates on an annual budget of $17 million. It was incorporated in 1937 by an act of Congress of the United States under Public Law 358 and signed into law by President Roosevelt.

Our interest in presenting views on the subject before the committee today might be made clear by quoting the purposes of the society from our charter. These are, "that the objects of the incorportion shall be to encourage in the broadest and most liberal manner the advancement of chemistry in all its branches; the promotion of research in chemical science and industry; the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education, and attainments; the increase and diffusion of chemical knowledge; and by its meetings, professional contacts, reports, papers, discussions, and publications, to promote scientific interests and inquiry, thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

This is a quotation from the incorporation.

I personally support this mission of the American Chemical Society to help chemistry serve the American people and improve the general welfare.

I am sure that the general objectives of everyone participating in these hearings are undoubtedly similar, whether they are speaking for themselves or representing large organizations.

I think all of us want the United States to utilize its discoveries for the greatest benefit of its people.

But there are obviously honest differences of opinion as to the best way to accomplish this general objective. And we in the society have reviewed the proposed legislation which is before the subcommittee, and we would like to comment a little later specifically about S. 1809, sponsored by Senator McClellan; S. 1899, introduced by Senator Long; and S. 789, introduced by Senator Saltonstall.

We might say to begin with that we find the first two of these generally acceptable, but do not find that introduced by Senator Long acceptable in our view.

I would like to just say a word or two in the introduction about the interest of chemists in patents.

It seems to me from what has been said at these hearings and elsewhere that there are certain misunderstandings about the main purpose and significance of a patent. I would like to just interject that patents are of great interest to chemists. There are more chemical patents every year than there are any other single branch—I think some 22 percent of the patents are issued for chemical processes or products.

As the Constitution states, the purpose of the patents system is to "promote the progress of science and the useful arts." This is accomplished by encouraging the creation of useful innovations, by providing an environment of limited protection to the first to create new ideas, so that the inventor is encouraged to develop the bare idea to a

statement, in the deferred situation, a contractor (normally a company without a commercial background) can usually expect to obtain title if it can show a positive plan for commercializing the invention. However, the burden is on the contractor to show the plan, and on the Government to decide whether fundamental public policy requires that title vest in the Government. In particular, this kind of decision should not be subject to judicial review. Judicial review may be appropriate to procedures which have as their purpose divesting rights previously established. However, here the issue is the allocation of rights in the first instance, a procedure substantially different from divestiture.

In general, however, we would favor enactment of S. 1809, if changed in accordance with our recommendations. We believe that this bill can be interpreted to preserve the administrative flexibility which is contained in the President's policy.

With respect to the other bills before the subcommittee dealing with Government patent policy, the Department of Defense considers that S. 789 contains desirable features but falls short of certain important provisions of the President's statement and therefore the Department does not recommend its enactment. For example, S. 789 would limit the exercise of "march-in" rights to cases in which the Government might have acquired title at the time of contracting but did not. This is more restrictive than the President's statement. We believe that "march-in" rights should be available in any case in which the Government has obtained only a license.

The Department of Defense strongly opposes enactment of S. 1899. This bill would be in effect require the Government to take title to all inventions and applicable patents emerging from federally financed research and development. Such a policy would have, in our judgment, severly adverse long-range effects on the Defense research and development program. It would tend to concentrate our work in only those firms which take our contracts on any terms they can get them and to cut defense work off from the best research work carried on by U.S. companies for their own commercial purposes. It would discourage inventive small business from working for the Government. It would remove the patent incentive and protection for commercializing many inventions made for the Government.

While S. 1899 would provide for after-the-fact review of each invention—an exceedingly cumbersome administrative process—the requirements which would have to be met before a contractor could obtain title to his invention are such that in practical terms no patents would be acquired by contractors.

Our detailed comments on these bills have been provided in written form to the chairman of the Judiciary Committee.

Mr. Chairman, this concludes my statement. I am ready to answer any questions you may have.

Senator McClellan. Thank you very much, Mr. Malloy. Your letter from the Department to the chairman of the Senate Judiciary Committee, of course, will be made a part of the record, and we will have the benefit of that in the record as well as your statement today.

Senator McClellan. At the outset of your statement you emphasized the patent incentive as a consideration in procuring. What,

To illustrate the need for flexibility and the need to consider cases separately, one need only think of the wide variety of situations which can and do exist. For instance, if Federal money is used to build a completely new staff which will work on a Government-sponsored project, the rights to patentable discoveries obviously should probably reside with the Government. On the other hand, if such funds are directed toward a project whose personnel each had averaged 10 years of experience with the firm contracted to do the job, patentable results would not necessarily obviously become the property of the Government since the scientists and engineers doing the work must have used some of the know-how they had built up through their experience. Some consideration must be given to the employer who has been supporting and developing an efficient staff through the years before taking on the Government-supported project. In such cases it seems appropriate for each Federal agency to negotiate the best arrangement for all concerned as has been the practice in the recent past under the Kennedy patent policy of October 1963.

There are great differences in financing research leading to inventions. This might be represented at one extreme by the almost total Government support of, say, a large electrical company's missile and space laboratory, and at the other extreme, by a small grant to help a university or foundation research program. This raises the question of the difference in the mode of utilization of any consequent discoveries. Only the Government will purchase the results of research on the better space vehicle for the foreseeable future. But if my research on polymers, supported in part by Federal funds, produces a better foam rubber, or a better insulating plastic, this will be bought largely by private citizens from commercial firms, and then only if they are convinced of its merit over existing products. But in order to find out whether my better foam rubber will be practical and will be accepted by the public may require investment of many years and millions of dollars.

I can cite one example in history—the Talon fastener, which took many, many years of vigorous effort before the public was convinced that they needed a zipper in place of buttons.

In my own personal research during the war, my group developed a new procedure for the synthesis of the antimalarial drug, chloroquin, which I think remains today the best and most widely used drug for the treatment of malaria. Our synthesis was far more efficient and superior to the German synthesis. And through some Government contract funds, one company did some development work on trying to develop this procedure for making this drug. But under the terms of the program, the Government owned the patent and the patent would be dedicated to the public. The ultimate decision by this company was that they could not afford under these circumstances to risk several million dollars to build a plant, to prove that this was a better process, if anyone else could then step in and utilize the process. So for 20 years we have paid more for chloroquin because the old, inefficient German process is still used for its production.

In the case of my research on polypropylene-oxide rubber, this was done on university programs where the patent rights could be assigned to a company, and in this case the company did invest a great deal of

emerge from the contract work. The safeguards which I mentioned include the right to require the contractor to make the invention available to others for use or manufacture to the extent the invention is required for public use under a governmental regulation or to the extent it is necessary to fulfill health needs, and also the right to require the contractor to grant licenses to others if he refuses to commercialize his invention or permit others to do so on reasonable terms within a reasonable time.

The President's statement strikes a proper balance between complete public ownership or complete private ownership of inventions and applicable patent rights which result from performance of research and development work financed by the Government. In addition—and I emphasize this—it provides the administrative flexibility which is essential if the various agencies of the Government are to execute their primary missions and at the same time achieve a consistency in patent policy in areas of endeavor common to several agencies.

The Department of Defense patent policy fully implements President Kennedy's statement of patent policy. It is interesting to note what has happened in terms of division of patent rights. Operating under the old Defense policy, 17 research and development contracts in fiscal year 1963 contained a clause acquiring title to the patents for the Government. In fiscal year 1964 the number of such contracts increased to 29, making a total of 46 such contracts in fiscal years 1963 and 1964. The remainder, more than 99 percent, contained the license clause. In contrast, under the ASPR implementation of the President's statement, for the month of April 1965 alone, out of 695 research and development contracts awarded, 68 contained the title clause, 505 the license clause, and 119 a clause which defers the allocation of rights of inventions until disclosure, and 3 did not contain patent clauses (because the subject matter made it unnecessary to do so). In our opinion, these figures demonstrate the marked swing from what was substantially a hundred percent license policy to the more balanced result which was intended by the President's statement.

Nevertheless, we are well aware of the need to improve the implementation of this policy by our contracting officers. They have decisions to make which they have never had to make before. These decisions are not easy. We have several thousand contracting officers located all over the United States, and we are continuing our efforts to impart to each one a common understanding of the Department of Defense implementation of the President's policy. In addition we believe that further revision of the regulations to assure clarity and consistency is necessary, and we expect that changes will be made as a result of analysis of our operating experience.

However, we have enough experience to form the firm opinion that President Kennedy's statement of patent policy is the soundest formulation of policy ever achieved in this most difficult field.

The Department of Defense therefore supports legislation which incorporates the patent policy stated by the President. Because, Mr. Chairman, your bill S. 1809 in large part does this, the Department of Defense supports it.

if, inter alia, the invention is not, or is not about to be, placed in commercial use.

We agree that there should be a provision to make certain that inventions are used, if they are useful to the public. While provision is made for obtaining an extension of time, the 3 years allowed is considerably short of the interval commonly required for the development of chemical processes and products.

So, as I say, while this general principle seems reasonable, we believe that significantly more time should be allowed the contractor to evaluate fully the commercial potential of an invention and something of the order of 5 to 7 years would seem reasonable to us, rather than the 3 years provided in Senator Saltonstall's bill.

In summary, the society vigorously opposes the basic principle of S. 1899 and supports the basic approach taken by S. 789 and S. 1809, on these very important matters of Government patent policy.

We express our appreciation for the opportunity to present our views. If there is anything we can do further to assist the committee in its investigation, we would be delighted to do so.

Thank you very much.

(The full statement of Dr. Price follows:)

STATEMENT BY THE AMERICAN CHEMICAL SOCIETY

Mr. Chairman, distinguished members of the subcommittee, my name is Charles C. Price. I am the chairman of the department of chemistry at the University of Pennsylvania in Philadelphia, Pa., and president of the American Chemical Society. I appear before you today in the latter capacity. The society is an organization founded in 1876. It is the largest membership organization devoted to a single science in the entire world. Its annual budget exceeds $17 million. Incidentally and importantly, it should be noted that the society was chartered by the Congress of the United States under Public Law 358, 75th Congress, chapter 762, 1st session, and signed into law by President Roosevelt on August 25, 1937.

Our interest in presenting the views of the society on legislation to establish a Federal patent policy is based primarily on our charter, paragraph 2 of which states as follows:

"SEC. 2. That the objects of the incorporation shall be to encourage in the broadest and most liberal manner the advancement of chemistry in all its branches; the promotion of research in chemical science and industry; the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education, and attainments; the increase and diffusion of chemical knowledge; and by its meetings, professional contacts, reports, papers, discussions, and publications, to promote scientific interests and inquiry, thereby fostering public welfare and education, aiding the development of our country's industries, and adding to the material prosperity and happiness of our people."

GENERAL OBJECTIVES

The general objectives of everyone participating in these hearings are undoubtedly similar whether they are speaking for themselves or representing large organizations. Everyone wants the United States to utilize its discoveries for the greatest benefit of its people. But, there are honest differences of opinion as to the best way to accomplish this general objective. The society has reviewed the proposed legislation and will have some comments to make on each bill under consideration; namely, S. 1809 by Senator McClellan, S. 1899 by Senator Long, and S. 789 by Senator Saltonstall. We find the first two of these generally acceptable, but not that introduced by Mr. Long.

have been debated so vigorously, so thoroughly, and for such a long time. The several hearings your subcommittee has conducted on this point have made you thoroughly acquainted with the opposing viewpoints. The Department of Defense presented its views to your committee in 1961, and we reaffirm those views today.

Suffice it to say that the mainspring of the patent policy which the Department of Defense has followed has been incentive. In contracting for national defense research and development the Department of Defense has sought, among other things, to take advantage of the incentives implicit in the patent system. The patent system was established to encourage invention, disclosure, and exploitation of new ideas. It is a fundamental part of the economic framework of incentives in which American industry operates.

When the Department has agreed that contractors and their subcontractors may retain patent rights in inventions they make in performing research and development under Defense contracts, provided the Government obtains complete rights to use the inventions itself or to have them used by others in work for the Government, the Department has hoped to maximize the incentive to both large and small companies to seek out and compete for Defense work, to bring their best privately developed background and most promising ideas and most talented people to the task, and to report freely and readily the full results of their work, without fear of losing exclusive commercial rights in their ideas, which would normally be theirs.

The Department has acquired what it bargained for. To accomplish its purposes the Department has not generally needed full title to its contractors' inventions, and it has believed that requiring full title would undesirably dilute a necessary incentive for Defense work. At the same time, it has considered that when the invention remains in private hands, the incentives of the patent system are available to protect and encourage private investment in bringing inventions made in Defense work to the commercial market and thus making them available to the general public.

However, the Department of Defense has long recognized that its general policy of seeking only a governmental license to use its contractors' and subcontractors' inventions is not necessarily the only appropriate policy for the entire Government. Other Government agencies have different missions and roles to play in the national economy, and these different missions and roles may require a different patent policy. In other words, in these instances there may be a specific governmental purpose to be served in taking title. For example, while the Department of Defense does not contract to develop inventions for commercial use—and inventions found useful for military purposes often require considerable private investment to make them commercially useful—other Government agencies do have a mission of developing inventions to the point of commercial application and making them available to an industry without the need for further development. The research and development in commercial fertilizers carried on by the Tennessee Valley Authority is an example of this kind of agency mission.

In 1961, following prolonged congressional interest in the patent policy question, the Department of Defense formally recognized in

would not necessarily obviously become the property of the Government since the scientists and engineers doing the work must have used some of the know-how they had built up though their experience. Some consideration must be given to the employer who has been supporting and developing an efficient staff through the years before taking on the Government-supported project. In such cases it seems appropriate for each Federal agency to negotiate the best arrangement for all concerned as has been the practice in the recent past under the Kennedy patent policy of October 1963.

There are great differences in financing research leading to inventions. This might be represented at one extreme by the almost total Government support of, say, a large electrical company's missile and space laboratory, and at the other extreme by a small grant to help a university or foundation research program. This raises the question of the difference in the mode of utilization of any consequent discoveries. Only the Government will purchase the results of research on the better space vehicle for the foreseeable future. But if my research on polymers, supported in part by Federal funds, produces a better foam rubber or a better insulating plastic, this will be bought largely by private citizens from commercial firms, and then only if they are convinced of its merit over existing products. But in order to find out whether my better foam rubber will be practical and will be accepted by the public may require investment of many years and millions of dollars. Some incentive for this large investment is necessary, one of the important reasons, the society believes, for the constitutional rights granted to patentees. It is important to emphasize that a profit is made on the investment of research and development funds only if the public finds the product useful and buys it. For example, I have been told that during the past decade a major company invested $10 million in a new product only to have a competitor produce a superior one, thereby making this expenditure virtually worthless.

COMMENTS ON THE PENDING LEGISLATION

As is evident from the foregoing, the American Chemical Society believes that there are two major public benefits stemming from patents: (1) The stimulation of disclosure of new scientific and technical information; and (2) providing incentive for the frequently massive investment necessary to convert an invention into a product available to the public.

The second of these purposes would be seriously undermined and controverted by the basic philosophy inherent in S. 1899 (Long bill).

Furthermore, we believe that section 4(a)2 of S. 1809 (McClellan), in fact, would serve the same undesirable purpose for the area of "public health, welfare, and safety" and therefore urge deletion of this principle. If incentive for investment necessary to make inventions available to the public is necessary in other areas, it should certainly be available to stimulate development in such vital areas as health, welfare, and safety.

The society also would like to comment on section 6 of Senator Saltonstall's bill, S. 789. This section states that the contractor's rights in an invention under section 3(e) may be voided by the Government if, inter alia, the invention is not, or is not about to be, placed in commercial use. While provision is made for obtaining an extension of time, the 3 years allowed is considerably short of the interval commonly required for the development of chemical processes and products. The general principle evident in this portion of S. 789 seems reasonable to the society, but it believes that significantly more time should be allowed the contractor in which to evaluate fully the commercial potential of an invention. As a guide, an interval of 5 to 7 years is not unreasonable in such situations.

In summary, the society vigorously opposes the basic principle of S. 1899 and supports the basic approach taken by S. 789 and S. 1809.

We thank you for the opportunity to present our views, and assure you of the society's willingness to cooperate with the committee as it continues to investigate the vital topic of Federal patent policy.

Senator MCCLELLAN. Just two questions.

On page 4 of your written statement you say:

We feel that the rigidity called for by S. 1899 would not result in the greatest usefulness and benefit to the general public.

Why?

S. 789, S. 1809, and S. 1899 each deals with the acquisition, disposition, and use of inventions and data resulting from contracts directly concerned with research and development financed at taxpayer expense. None of them reaches the situation where negotiated contracts result in substantial public support of the independent research programs of contractors through the assumption of such research costs in overhead rates. Under current administrative policies, the Government does not, so far as we know, obtain any rights with respect to inventions and data financed at taxpayer expense in this manner. We are not in position to make any recommendation concerning the proper policy to be followed. But the question of indirectly Government financed research and development is closely connected with the subject covered by the three bills, and we believe there is sufficient at stake in the way of Government funds involved and inventions made to warrant bringing the matter to your attention.

(Mr. Welch then testified with respect to S. 1047 which is being printed separately.)

Senator BURDICK. Getting back to another portion of your testimony, you referred to S. 789, S. 1809, and S. 1899, and you state, "none of them reaches the situation where negotiated contracts result in substantial public support of the independent research programs of contractors through the assumption of such research costs in overhead rates. Under current administrative policy, the Government does not, so far as we know, obtain any rights with respect to inventions and data financed at taxpayer expense in this manner."

Can you give me an example of that type of situation?

Mr. WELCH. Could I have Mr. Rubin answer that question? He is with our audit group.

Senator BURDICK. Yes.

Mr. RUBIN. The situation described here is a situation where a contractor has a so-called independent research and development program. The Government will negotiate with a contractor in advance as to the extent of the program which the Government will be willing to participate in through inclusion in the contractor's overhead as an allowable item of cost. This cost is then allocated to the contracts then in process which may involve production or research and development. The Government participation may cover as much as 80 or 90 percent of the contractor's costs.

The extent of the independent research programs is rather significant in many cases. We have received an estimate made within the Department of Defense that indicates that the amount of the total of such programs, I think about a year or two ago, was in the neighborhood of $900 million annually. That is a rather significant figure.

Senator BURDICK. I do not quite understand it yet. The Government pays a consideration to the contractor to do this work.

Mr. RUBIN. The Government, you say, pays a consideration?

Senator BURDICK. Yes.

Mr. RUBIN. The Government will pay for a share of it; yes.

Senator BURDICK. What is the difference between a regular and a development contract?

Mr. RUBIN. The point that we make here is that the way these bills read they relate only to contracts directly concerned with research and development. These contracts will not specifically provide for

Dr. PRICE. You cannot get along without it now, Senator. But it took 10 years to convince people——

Senator MCCLELLAN. What type of a terrible time did he have?

Dr. PRICE. It took a long time to convince people that this was not a dangerous weapon but a useful invention. And literally this man had a terrible time to convince people.

Senator MCCLELLAN. That is a very vivid and convincing illustration in my mind.

Dr. PRICE. But this happens for all kinds of discoveries—it is a very rare scientific discovery that is made for which everybody says "Ah, this is just what we were waiting for." For example, many kinds of rubber were available in 1949 so it took lots of convincing that our rubber was going to turn out to be a much better product.

Senator MCCLELLAN. That is one illustration. Can you give another?

Dr. PRICE. Well, I think my chloroquin antimalarial drug is another illustration on the negative side. I am firmly convinced that the process we had developed, which was, in this case, actually taken through a development stage at Government expense, was clearly more efficient and more economical as a procedure for making this compound than the existing one. Yet it was not reduced to practice. The money to invest in a plant——

Senator MCCLELLAN. Would you hold your answer a minute? I have somebody on the telephone I must speak to.

I am sorry. Go right ahead.

Dr. PRICE. As to this rigidity of the Long bill, it seems to us there are very great differences in how an invention might be made useful to the public. There are some—for example, if you have the cure for the common cold—that everybody will want to buy it immediately. But there are many other inventions which prove to be extremely useful, but which when first discovered are not obviously useful, and it takes a lot of faith, a lot of conviction, and a lot of investment of effort before it can be proven that these inventions will be useful to the people. And we believe there ought to be some flexibility to provide these incentives in a variety of different situations.

We think that the Long bill is a little too rigid in not providing enough incentive for some of these situations.

Senator MCCLELLAN. Now, one other question.

You may have already answered this. The answer you have just given may have covered this.

You said on page 5:

As is evident from the foregoing, the American Chemical Society believes that there are two major public benefits stemming from patents.

Then, No. 2:

Providing incentive for the frequently massive investment necessary to convert an invention into a product available to the public.

And you say:

The second of these proposals would be seriously undermined and controverted by the basic philosophy inherent in S. 1899.

Did your previous answer cover that?

Dr. PRICE. I think, essentially——

Senator MCCLELLAN. Did not your previous answer cover that?

Senator McClellan. I have tried to say repeatedly that I have no unyielding conviction with respect to the issues involved in this legislation. I think that the Government's rights and the taxpayers' rights should be amply protected, but there is one aspect that is quite persuasive, may be conclusively so with me and, that is, that the Government goes out to a company that has built up a wide experience in a given field, has mobilized the know-how, has it in place and ready, and the Government says, "in this particular area we would like to have a given thing—we will help finance it—we will finance it, we will give you a contract to go right to it and put on a crash program and get this thing done for us."

Now that same company might very well prefer to use its research, its skill and know-how for application to something of its own or to continue on with what it is doing, and thus reap the full benefit from that effort. But there are those who are contending, apparently, that if the company enters into a contract with the Government allowing it to take full advantage of all of that which has been done to bring the research in that area up to its present state so that it becomes the foundation for the new research, and if the Government puts in a dollar or anything then it ought to have all of the patent rights that ensue therefrom. I do not think that is equitable. And that is the thing that gives me concern. Where the Government provides all the funds and starts some new experience and does not get the advantage of something that has already been accumulated there may be some justification for pursuing the patent rights, there may be some justification for stating that the patent rights should go only to the Government, and that the Government should take it and make it available to anyone who wants to use it. I have simply tried to get the best evidence and information that we can to help us establish the equity as nearly as it can be done between Government and private enterprise in this field, to establish adequate protection for the taxpayers, and as the politicians often say, to protect their tax money—to protect their interests—and at the same time to be fair and to be just to those who made investments on their own and have taken the risk in the private enterprise field and have developed to a point where it becomes a great asset, the framework, so to speak, for the goals that the Government seeks and needs.

And if someone has said that this is simple, I do not believe that they know very much about the problem, because it is not simple, it is not easy to find the proper solution to this. I think you have made a very fine contribution to the record of this committee which we will have to carefully study. I, personally, appreciate your presence and the time that you have given us.

Mr. Daddario. Thank you, Mr. Chairman, for those remarks.

I would like you to know that with some slight modifications it is my intention in the near future to submit a bill quite comparable to S. 1809 in the House.

Senator McClellan. I am sure that S. 1809 may need some revisions and it may well form the basis for the legislation that this committee will report, and it may not. I do not know, but, in any case, it was the best that I could find at the time of introduction. I think that this is a matter of some urgency. There is no disposition on the part of this committee as I indicated in my opening statement to try to expedite this legislation without giving it the attention and the study

Senator McClellan. The difference I am interested in here is where the Government goes out for the specific purpose and provides research funds in order to develop drugs that are beneficial to health. Very well. The Government finances research to develop a better airplane or something like that, and in the course of that it gets the product it wants, but there is a byproduct or a fallout product of a discovery or an invention—and in those instances I think the Government could very well let private enterprise have it, take it, and develop it and get it on the market if it has a civilian use or a general consumer use.

But when the Government specifically finances the experimentation and the development of drugs to effectuate a cure of disease, I think there is a little difference—it comes in a little different category.

Dr. Price. Well, the Government finances research, which leads to the discovery of a better cure of some disease, and this is the invention. Now, somebody wants to buy this thing from a drugstore shelf. The question is, How do we go from the discovery to the product which you and I can buy on the drugstore shelf?

Now, in many cases, in drugs as well as in the new rubber or a new plastic—or any other product, there is a question whether this drug will prove to be better, and there is a vast investment necessary—I am a consultant for the Eli Lilly Co., and I see the immense expenditures it takes to take a new drug that you have discovered that shows some beneficial possibilities in animal tests, to find out whether that drug is going to be useful in human beings—this again requires a vast investment. And it seems to me that you need to provide an incentive for that investment just as you need to provide an incentive for the investment to develop other new products for the public.

Now, I think the Government has a very great responsibility to regulate the use of drugs. But I think that there is need, and I think it is important to consider this—I can be wrong, of course, Senator—but you asked my opinion. In my opinion as a chemist, there is just as much need for an incentive to develop a new drug as there is incentive to develop a new rubber.

Senator McClellan. I do not know any of us who could not be wrong. Very well.

Senator Burdick.

Senator Burdick. One of the things that puzzles me about your testimony is that you speak of incentives. Yet the Talon fastener that you refer to, most anything else, comes out of the human mind—that is where it comes from. You are perfectly willing to deny to a man who has spent a lifetime in science any patent rights at all for the work that he accomplishes for working on a Government contract, are you not?

Dr. Price. I am afraid that I do not understand.

Senator Burdick. All right. Company A hires a scientist who has been working in your university for all his life. He is put on a project X. There he makes a discovery. That man gets no patents rights for his work. He is the one that should be stimulated—he is the one that should have the incentives. Is that correct?

Dr. Price. I understand. Yes, I think what you are saying is that when a man goes to work for a company he no longer privately

many "in between" cases, it would be possible to work out an equitable arrangement of exclusive licensing or whatever degree thereof appeared appropriate.

I should like to emphasize that the executive agencies which must deal with the patent problem on a day-to-day basis, without exception, have learned the importance of the kind of flexibility which S. 1809 would provide. Even those agencies which have been required or most prone to exert title in the Government, such as the Atomic Energy Commission, the National Aeronautics and Space Administration, and the Department of Health, Education, and Welfare, have found it necessary to alter their practice according to the individual circumstances. You have heard much about the desirability of the practices of the AEC policy from those who favor a rigid Government-ownership position. Yet, if you look at the 1964 annual report of the AEC for the Joint Committee, you will find considerable variation in patent treatment. AEC now holds about 3,000 patents. On these it has granted nonexclusive licenses to over 1,000 private firms; 561 have been retained by contractors; 330 exclusive licenses have been granted in "outfield" cases; and title to 400 patents has gone to contractors, subject only to a Government license.

Certainly this, it would appear to me, is persuasive evidence of the need for flexibility in whatever system is adopted.

I should like now to turn to several somewhat more specialized aspects of the patent policy problem.

One of these is the international phase, which has not been widely discussed. We have heard much about "giveaways." But a most vulnerable "giveaway" condition occurs in regard to foreign rights when our Government takes title to inventions.

Let me explain. According to U.S. patent law, an application for patent must be applied for by the inventor himself. The Philippine Republic is the only other country in which this is required. In countries such as England, France, or Germany, or many of the Latin American countries, a patent may be obtained by a person who brings the invention into that country even though he imported it from another country such as the United States.

Thus, when inventions are freely available to the public in the United States, we are powerless to stop people in other countries from obtaining patents in other countries of the world on the basis of inventions made in the United States by American inventors. When this happens our own Government cannot use the inventions on which the patents are obtained, and even the American contractors or inventors who were responsible for making the inventions cannot practice them in those countries without infringement or obtaining a license. And this at a time when our balance-of-payments situation is critical and of immense economic importance.

Another aspect of the problem concerns the so-called advance waiver. You may and probably have been told that there is no excuse for waiving title on an invention not yet in being. In the main, I tend to agree with this position. And yet there are situations where it is most beneficial to the Government to be able to waive in advance. I refer to cases where a Federal agency, having discovered that some potential contractor has already done considerable private research in an area vital to the interests of the Government, approaches that con-

tion that is carried out in the Du Pont Co., in the General Electric Co., in Hercules Power, in Lilly, and so on, that is available because of the patent laws.

So one is this disclosure of scientific information. And this is a great satisfaction, incidentally, for the scientists. We like to see what we have done, see the light of day. And I can assure you that the publication of the work as a patent or as a paper which is made possible by the patent law is a public benefit, but also a private satisfaction to the inventor.

Second, the other public benefit is this business which I have emphasized so much, the incentive to get the investment into development—take the bare invention and make it into a product. And I think these are the public benefits that are important, and it is the vast investment of Government funds in research and development that now make this a very important public policy decision, as to how the use should be made of these patent rights.

Senator BURDICK. If the Government retains the patents, there is a wide-open field for the public to develop that patent; is there not?

Dr. PRICE. If the Government owned the patent?

Senator BURDICK. Yes. Everybody has a right to it.

Dr. PRICE. Everybody has the right to it, but nobody has any incentive to invest in its development if it is not obvious that this is a major breakthrough. There will certainly be some patents, I agree—there will be some patents like, we could say, the cure for the common cold. If you could find a way to cure this, every drug company would make it, and every drug company would want to have it in its line of products, and if it was available as a Government patent, they would do it whether it was exclusive or not.

But for many, many products this is just simply not the case. It is not obvious that this is going to be better until it is out and tried.

Senator BURDICK. Well, certainly the public will have a better opportunity to develop a patent if they know about it than if they do not know about it and cannot develop it, if it is controlled by somebody.

Dr. PRICE. Everybody knows about a patent the minute it is published.

Senator BURDICK. They do not have the right to develop it.

Dr. PRICE. They do not have the right to utilize it unless they get a license to do so.

Senator BURDICK. I must respectfully disagree with you, sir. I think if the patent is available to the public, the development possibilities are greater than if they are hemmed in some way.

Dr. PRICE. I think the concern I have is that the public will not and cannot spend $5 million or $10 million to take the invention and make a product out of it.

Senator BURDICK. Some smart entrepreneur will do it, a businessman.

Dr. PRICE. But he will have to prove it with a $10 million investment. If somebody else can then come in after it is proven, and after he has developed it, and make it for a fraction of that, it does not make sense to me.

Senator BURDICK. Just a moment. There is $5 billion to $15 billion involved here. The taxpayers of the United States have some money

STATEMENT OF HON. EMILIO Q. DADDARIO, A REPRESENTATIVE IN CONGRESS FROM THE FIRST CONGRESSIONAL DISTRICT OF THE STATE OF CONNECTICUT

Mr. DADDARIO. Mr. Chairman and members of the committee, I am grateful for the opportunity to appear and present my views on this most important subject.

As you, Senator McClellan, have recently been pointing out on the floor of the Senate, anything associated with patents is likely to be a highly complex matter, and a Government-wide patent policy is assuredly so. I wish to compliment this committee for its wisdom in treating the matter accordingly—and not in the simple black-and-white fashion which some people at both ends of this issue tend to advise.

It is not my intent here, today, to recite the history of the Government research patent problem, nor to discuss facts and figures, nor to present you with isolated cases in point designed to prove an argument. You have already been exposed to such discussion, and adequately, I am sure.

But I would like to summarize my philosophy on the Government-owned patent question—a philosophy which I believe is shared by many of our colleagues. It is also a philosophy which has emerged from a good deal of interest and time spent in study and hearings.

As you may know, I have chaired a special subcommittee which was charged with the duty of reviewing the Government patent relationship in connection with our national space program. We spent better than 4 years on the subject between 1959 and 1964; we issued three major reports, reported out two bills amending the National Aeronautics and Space Act patent section and passed one of them through the House. So, while I am not a patent lawyer and make no pretense of being an expert in regard to the patent system itself, I am familiar with the issues surrounding Government patent policy.

Mr. Chairman, I have three main basic convictions which I should like to submit to you and your committee on this matter.

First—it is very clear to me that where federally financed research and development is concerned both the Government and contractor have logical and justifiable equities in the ownership of such patents as may arise in the course of the contract.

It is idle to pretend that the Government, at least in its role of representing the public, has no reason for nor interest in the title to such patents. Without the use of the taxpayers' funds the patent might not evolve in the first place—and the fact that the United States always has a free and irrevocable license to use the patent item or to have it produced by any party it chooses for governmental purposes is not always sufficient to protect the public interest. By the same token, it is equally unrealistic to assert that the contractor, who may have contributed as much or more than the Government in terms of know-how and the expenditure of its own money toward the development of the patent, has no claim to ownership nor the exclusive right to utilize the patent for commercial purposes. To take the latter position may be unfair to the large contractor and, in addition, downright disastrous to the small contractor, to whom a patent portfolio is an important

Dr. PRICE. No, sir; only under the NIH policy, which I vigorously disagree with. In other agencies they will assign—in fact under a Quartermaster grant, we did develop a very interesting new synthetic plastic, polyxylenol. We are now in interference with a small concern by the name of General Electric as to who is going to get the patent rights on this. They published it a year after we did. But we do not yet know who will get the patent.

But under the Quartermaster, we made an agreement that the Government would have a royalty-free right to use an invention that was made. But we had the right to exploit the private commercial development of this material. The University of Pennsylvania has in fact taken my patent, which I assigned to the University of Pennsylvania, and taken it to a company to see if we can exploit this invention.

Senator BURDICK. Was that developed under Government research?

Dr. PRICE. Yes, sir, under the Quartermaster Corps. I think it is only the NIH where we have no rights residing with the inventor.

No, I like to see the rights reside with the inventor, by all means. This is what I am arguing for. So he can take his invention and bargain with somebody to make use of it.

Senator BURDICK. I am not arguing—I am just pointing out the inconsistency of the company getting it and denying it to the people who do the work.

Dr. PRICE. I think the inconsistency is not there, because I do believe that the whole philosophy of the patent law is that the invention goes to the inventor. He is the one who applies for it and he gets the patent rights.

What he does with it to see that it is made use of differs according to the situation.

In my case, as a professor, I can bargain with it a little bit to see who can make use of it. If I am already working for a company, I have signed an agreement that the inventions I make will automatically be assigned by me to the company in exchange for my salary and other rewards.

Senator BURDICK. Now, you say you are a consultant to Eli Lilly & Co. Suppose that company "A" makes a contract with company "B"—this is purely private—and company "A" has asked "B" to do a research project for them—maybe on a subcontract basis or some other basis. What is the usual practice? Does A or B have the patent rights of any discoveries made there?

Dr. PRICE. Well, I think this is usually a matter of a great deal of concern by the lawyers who write the contract.

Senator BURDICK. I am asking you the practice.

Dr. PRICE. I would think that the practice usually is that the company that provides the money would usually get the rights to develop this.

Senator BURDICK. That has been the testimony before this committee—that A would retain the patent rights.

Dr. PRICE. And if the Government was going to develop and sell the patented inventions, I say the philosophy might be that the Government should have the rights to the patents it finances. But I do not think it will ever develop and sell them under our present economic system.

APPENDIX

Dr. WAKERLIN. The American Heart Association deeply appreciates the opportunity you have extended to us to voice our views on the disposition of invention rights in connection with discoveries arising from research activities jointly supported by Government and private funds.

We of the American Heart Association are fully cognizant of the committee's need to arrive at some general patent legislation to protect the public, as represented by the Government's research investment, while also protecting the rights of private organizations. We also realize that such general legislation must be designed to apply to scientific discoveries in such diverse fields as space and defense as well as to scientific discoveries in the field of health in which we have our prime interest.

Nevertheless, in appearing before you we would hope to make you aware of certain technical problems peculiar to medical research which we are sponsoring in the public interest.

Scientific research activities performed in universities and institutions often receive joint and contemporaneous support from commingled funds from two or more sources. Indeed, the U.S. Public Health Service, on many occasions and in the public interest, has encouraged support of research from the private sectors of the economy of this Nation and discouraged exclusive reliance upon Government-financed support. While we heartily agree with this concept, its fulfillment frequently creates a difficult problem. The Public Health Service in its regulations requires that its research grantees agree to transfer to it ownership rights of all inventions. Similarly, the American Heart Association asks its grantees to agree to the assignment of invention rights to it. This at times creates a dilemma for the researcher. And yet only a small fraction of 1 percent of research projects leads to patentable discoveries.

It is no answer that the difficulty may be left to litigation; neither is it a satisfactory solution that the scientists be limited to acceptance of research support from only a single source. It would be infinitely better to provide a method for the equitable disposition of proprietary rights in any discoveries, since the Public Health Service and the American Heart Association both have the benefit of the public as their prime objective.

Assuming that the voluntary health agency has made a substantial investment of public-contributed funds, it should be within the discretion of such agency to achieve fullest public benefit by encouraging all possible development of such discoveries. It follows that there might be instances in which it might be advantageous to the agency and the public to achieve necessary development and application through recourse to financial and specialized manpower resources of a commercial organization. To assure this benefit, it might be necessary to offer the commercial organization leadtime—a reasonable number of years of exclusive license from the date of public introduction of the product—to recoup its developmental investment. The voluntary health agencies believe this to be a practical policy, for the alternative might be to use their own funds to contract commercially for this service on a cost-plus basis. This, in the end, might prove to be considerably more costly to the public.

In consideration of this point of view, it is our hope that any patent regulation bill reported on by this committee will empower the Department of Health, Education, and Welfare to enter into an agreement with publicly supported health organizations for the equitable disposition of proprietary interests in discoveries arising out of research projects in which both were grantors.

Thank you.

Senator McCLELLAN. In the last paragraph of your statement, what you would like to have is the Department of Health, Education, and Welfare authorized to grant exclusive license to any discovery made, where they have financed the research?

Dr. WAKERLIN. The "they" means who, Mr. Chairman?

Senator McCLELLAN. The Federal Government or the Department of Health, Education, and Welfare—where they advance funds for research.

If I understand this, you want the right reserved to that Department to make an agreement with publically supported health organizations for equitable disposition or for proprietary interests in discoveries "arising out of research projects in which both were grantors." In other words, to negotiate or work out an arrangement that would be satisfactory to both.

Dr. WAKERLIN. Yes; that is right.

Senator McCLELLAN. In other words, leaving the discretion in the Department. That is what it amounts to.

Dr. WAKERLIN. That is correct.

Senator McCLELLAN. As to how it will contract for or about proprietary rights where it provides all or some of the research funds.

Dr. WAKERLIN. For example, if it should happen, which is not too common, that the American Heart Association contributed a major part of the research support for a given project which resulted in a particular discovery, and the Department of Health, Education, and Welfare, or more specifically the National Heart Institute contributed a minor part, the negotiations might result in the patent right being assigned to the American Heart Association, which would administer it in the public benefit, of course.

Senator McCLELLAN. In that respect, now, here is our difficulty, as I see it.

It is impossible to write a statute with a formula in it that would cover each specific case or discovery or arrangement without leaving some discretion in the agency of Government involved. I do not know how we can do it, except to make a completely rigid Government take all, or that you set up guidelines whereby under those circumstances the Government may grant an exclusive license or grant the proprietary rights—but even where you set up guidelines—a great measure of discretion must be reposed in the Government agency involved, as I see it.

I do not know how you can write a rigid formula that would be applicable to each case. I just do not know how you can do it.

Dr. WAKERLIN. Mr. Chairman, we do not seek a rigid formula.

Senator McCLELLAN. I know you do not. But I am saying while it would be desirable if it could be done, just to spell everything out in the statute, in the law itself, I do not believe it can be done.

The further we go into this inquiry and study the subject, it seems to me as though it develops that it is just impossible to write a formula that would be applicable, that could say yes or no in each case. You have to leave a measure of discretion.

Dr. WAKERLIN. That I would agree with, sir. This is what the American Heart Association is asking be written into the legislation.

Senator MCCLELLAN. That is the way I interpreted the last paragraph of your statement—that you want some latitude, some discretion left in the Department of Health, Education, and Welfare.

Dr. WAKERLIN. I might say that we have always found negotiations on other matters with the National Heart Institute and other portions of the Public Health Service and the Department of Health, Education, and Welfare most satisfactory, most congenial.

Senator MCCLELLAN. In other words, you have had pleasant relations so far.

Dr. WAKERLIN. All through the years, sir.

Senator MCCLELLAN. You want to have it left that way.

Dr. WAKERLIN. That is correct.

Senator MCCLELLAN. That is what you are hoping for.

Dr. WAKERLIN. Indeed, yes.

Senator MCCLELLAN. Very well.

Senator BURDICK. Your funds are derived from Federal sources and private sources?

Dr. WAKERLIN. Our funds are derived from publicly contributed moneys, sir. In other words, we have a Heart Fund campaign which goes through the month of February, and certain contributions come in throughout the year. There are on occasion educational or community programs in the cardiovascular field where the National Heart Institute or the heart disease control program of the Public Health Service may contribute to the program and we contribute also. In that way, there is a certain amount of working together in terms of funds.

Occasionally the American Heart Association—this is exceptional—may for a specific project, where it seems more desirable for one reason or another to have the funds expended by the American Heart Association, on behalf of Government—has arranged for a grant from an agency of the Public Health Service. Thus, several years ago, the American Heart Association administered a travel grant from the National Heart Institute which enabled selected medical scientists to attend an important scientific meeting in Europe.

Senator BURDICK. Can you give me any breakdown of what percentage of the funds come from voluntary contributions, what percentage of the funds come from Public Health Service, what percentage of your funds come from private industry?

Dr. WAKERLIN. Money from the Public Health Service, sir, would be a fraction of 1 percent, and in some years it would be nothing. We receive contributions from industry—I cannot give you the exact percent. We have only one complaint about this, and that is we would like to have more funds contributed to us by industry.

The major part of our funds come from individual citizens and in small amounts.

Senator BURDICK. Would it be a fair statement to say that a majory of your funds come from contributions of citizens?

Dr. WAKERLIN. Yes, a very distinct majority, approaching 95 percent. Indeed, approximately $10 million was raised on Heart Sunday last February by door-to-door solicitation.

Senator BURDICK. And notwithstanding the fact that close to 95 percent of the funds come from the public by way of dollar donations $5 donations, and maybe 5 percent from private industry, you would like to grant this exclusive license to them for discoveries?

Dr. WAKERLIN. Only if this were necessary in order to be certain that a particular discovery was properly made available to the public. In other words, if the American Heart Association—on negotiation with the Department of Health, Education, and Welfare—did receive proprietary rights, the association would administer the patent in the public interest, and if that required giving leadtime to a commercial organization, we hope we might have the right to grant an exclusive license for a limited period of time in order to make appropriate development of the discovery possible.

For example, although penicillin was discovered in 1929, it became available only a good many years later when efforts were made to develop it, including pilot plant operation and then large-scale production. This required large sums of money and adequate facilities which are frequently available only to commercial organizations.

There might be other patents which would not require this kind of leadtime or exclusive license.

Senator BURDICK. Well, I share the chairman's concern to write a section in this law to do the things you want to do, with all the safeguards you would want, is a very difficult assignment.

Dr. WAKERLIN. Well, I think that if the chairman's suggestion is adopted, that Department of Health, Education, and Welfare officials are given authority to negotiate with voluntary health agencies who are in the research support field when the appropriate occasion arises—this would take care of the matter.

Senator BURDICK. I have a little concern for the people of the United States who put their dimes and nickels in there, too.

Dr. WAKERLIN. We do, too, sir. They are our lifeblood.

Senator BURDICK. That constitutes almost 95 percent of your contributions you say.

Dr. WAKERLIN. Yes sir.

Senator BURDICK. That is all.

Senator MCCLELLAN. Thank you very much.

Mr. BRENNAN. Mr. Howard I Forman, president of the Philadelphia Patent Law Association.

Senator MCCLELLAN. Very well, Mr. Forman.

I note you have a prepared statement. It is of some length. Would you be willing to file it and let it be printed in the record and highlight it for us?

Mr. FORMAN. Yes, sir. I will not refer to the statement as such today.

Senator MCCLELLAN. Beg pardon?

Mr. FORMAN. I would appreciate having my formal written statement filed in the record.

Senator MCCLELLAN. It may be received and published in the record in full.

(The prepared statement of Mr. Forman follows:)

STATEMENT BY HOWARD I. FORMAN

My name is Howard I. Forman. I am from Philadelphia, Pa., and my principal occupation is that of a patent attorney.

I appear today in a dual capacity: (1) as president of the Philadelphia Patent Law Association; and (2) as a private citizen who, as a taxpayer and a longtime student and critic of our Government's patent policies, is vitally concerned with the effects which the bills under consideration may have upon the public welfare if enacted into law.

With respect to my first capacity, I presume no statement of my qualifications is needed. As to my second role, I would like to briefly state my qualifications in an effort to establish justification for my claim to speak solely with the public interest in mind. I feel this is important because of a tendency of some persons in public life to belittle the views on Government patent policy matters of spokesmen who come from segments of industry or the patent profession, particularly if they happen to make their livelihood by serving industrial organizations not normally classified as small businesses.

I have been engaged in the practice of patent law for over 20 years, the past 9 in the employ of a corporate chemical manufacturer whose only Government contract in that period has been the operation of a small research laboratory for the Army. Prior to my present position my entire working experience, covering a span of 23 years, has been as a Government employee, as a clerk, as a chemist, and as a patent attorney. In 7 of the past 9 years I have been a lecturer in political science and public administration at Temple University, in which two fields I have had conferred upon me, the earned degrees of master of arts and doctor of philosophy by the University of Pennsylvania over 10 years ago.

My doctoral dissertation, incidentally, has been published as a book entitled "Patents—Their Ownership and Administration by the United States Government." It was based on my experiences while serving as consultant to the first Chairman of the Government Patents Board in 1950. Since then I have had published at least seven major articles, in law reviews, textbooks, or encyclopedias, on the subject of Government patent policy. A list of those publications is appended hereto. I am also the author of one other book and editor of two books dealing generally with patent law and practice, and author of approximately two dozen more law review articles on patents and related matters.

My views on Government patent policy, incident to which I have long exhorted the Congress to adopt a number of the proposals which have been incorporated in the bills under consideration, are a matter of public record. They appear not only in the publications on the attached list, but also in the records of the hearings on Government patent policy held before this same subcommittee (re S. 1084 and S. 1176) on May 31, 1961, and the hearings before Subcommittee No. 3 of the Committee on the Judiciary of the House of Representatives, on March 3, 1958, re House Joint Resolution 454 regarding the rights in inventions made by Government employees.

I submit that, in view of my background of government, university, and industry experience, with the past 15 years having been extensively devoted to studying, writing and lecturing on Government patent policy, my personal comments and suggestions which follow deserve to be considered on their merits and only on their merits. I do not feel beholden to any industrial organization or professional association, be it my employer or any group in which I hold membership, to express views or recommendations which necessarily coincide with theirs. In stating my personal views I speak only for myself, and disclaim speaking for any other person or organization with whom or with which I may happen to be or have been affiliated.

Reverting to my first capacity, I now wish to make a statement as president of the Philadelphia Patent Law Association, an organization of patent attorneys and agents whose active members reside or are employed in the eastern half of Pennsylvania, all of Delaware, and roughly the southern half of New Jersey. On behalf of that association's board of governors, it is my privilege to report on the following action which was taken at a meeting held in Philadelphia on May 27, 1965. This action, incidentally, followed a careful study and report of the four above-mentioned bills by the association's special subcommittee on Government patent policy.

PHILADELPHIA PATENT LAW ASSOCIATION,
BOARD OF GOVERNORS.

We believe that the progress of the useful arts is most effectively advanced when private enterprise is made secure in the exclusive right to what it has created. We believe that the machinery of government is ill adapted to the economic and effective exploitation of inventions in the civil field, and should not, on principle, compete with private enterprise, nor favor one enterprise as against another.

We believe, in short, that patent protection is an essential element of industrial progress, and that governmental ownership of patent rights leads to stagnation, because government, as such, is not in a position to enforce the protection which is a patent is intended to afford.

With these principles in mind, we earnestly commend the terms of Senate bill 1047, which would bring to an end the unauthorized taking of patent rights by government, except when national security requires.

With these principles in mind, we also earnestly commend the provisions of Senate bills 789 and 1809, but not in the precise form presently proposed. Rather, we very greatly hope that these two measures might be consolidated and then streamlined, in accordance with the accompanying recommendations of our committee on Government patent policy. If such a consolidation could be effected, the resulting system would be flexible enough to permit accommodation to widely varying circumstances.

On the other hand it is our view that S. 1899 is unduly rigid in its terms, and that it would provide a less effective means for stimulating real advancement, since it would increase the number of instances in which the patent would be owned by government, and would therefore afford no real protection to a licensee.

We authorize and request our president, Howard I. Forman, to present to the Senate Judiciary Committee, Subcommittee on Patents and Trademarks, the views expressed above and the specific recommendations of our committee on Government patent policy.

The foregoing statement was adopted by the board of governors, at a meeting held on Thursday, May 27, 1965.

WILSON OBERDORFER, *Secretary.*

PHILADELPHIA PATENT LAW ASSOCIATION,
COMMITTEE ON GOVERNMENT PATENT POLICY.

Your committee on Government patent policy offers the following recommendations:

S. 1047 (Williams, N.J.). This bill requires the Government to acquire a license before using a patented invention unless the Secretary of Defense certifies that the national security requires its use. We urge the board to favor the prompt enactment of this much needed legislation; in the hope that it will stop the wholesale emasculation of privately owned patent rights which has become a national scandal.

S. 789 (Saltonstall); S. 1809 (McClellan) and S. 1899 (Long) are all directed to the handling of patent rights in inventions made under R. & D. contracts. We shall compare their more important provisions in what follows:

We think that section 3 of S. 789, which provides that the Government shall always receive the free and nonexclusive right to use any invention made with the use of Government funds but shall take no greater right except under specified circumstances, is less likely to lead to unnecessary restrictions on creative industries than section 4 of S. 1809, which provides for the taking of broader rights (including title) unless certain specified circumstances justify exceptions.

We think that section 7 of S. 789, which calls for renegotiation only when subsequent and unforeseen events requires it, is sounder in principle than those provisions of section 4 of S. 1809 which require renegotiation every time an invention is made. The taking of greater rights under S. 1809 should be conditioned upon a finding that the public interest will be better served by such taking, in addition to the finding presently required, that the Government has the right to take.

We see no prospect of commercial exploitation of a patented invention owned by Government unless the Government grants an exclusive license, as provided by section 8 of S. 1809, but such a license is of little value unless it is implemented by the right to sue infringers. It seems anomalous to us that the Gov-

ernment should bring suit against one of its citizens for using a patent right which belongs to all citizens, or that it should gain the same result by indirection, by giving the licensee the right to bring such suit. For these reasons we urge that any legislation framed on this subject should be so drawn as to reduce to a minimum the situations in which Government takes title. For this reason, we favor the approach employed in S. 789, which leaves title with the enterprise that created the invention, but requires the patentee to license another if he fails to exploit the invention in nongovernmental fields within a reasonable time.

We respectfully suggest that section 11 of S. 789 be made the subject matter of a separate bill. That section deals with awards for inventive contributions, rather than with the subject of patent rights.

It is our hope that the desirable features of these bills can be consolidated into a practical, effective, and uniform system for the allocation of patent rights in inventions made under Government contract.

We are apprehensive that the very broad direction given in section 4 of S. 1899 might lead to a "Government take all" policy, which would discourage rather than promote invention. The waiver provisions of section 10 of S. 1899 are so stringent as to fully justify that apprehension. Nor do we see any need, at tremendous cost, to duplicate the information-gathering functions of the Patent Office and the Library of Congress, as contemplated by section 7 of S. 1899. We commend, however, the concept of a single authority to make policy determinations for all agencies, and the concept of giving the Board of Interference Examiners the duty to decide whether an invention was or was not "made" during the terms of contract and did or did not fall within its scope.

We add three very earnest recommendations as to terminology.

1. The expression "the conception or first actual reduction to practice" (sec. 2(g) of S. 1809) is one which often works a wholly needless hardship. Patent rights of incalculable value have been decided, in thousands of interferences, on a reduction to practice which was purely constructive; namely, the filing date of the application. We strongly urge that the word "actual" be deleted from this phrase.

2. The expression "at all tiers thereunder" in section 3 of S. 789 is potentially extremely mischievous and should be deleted. This could require the man who digs the foundations for a research facility to secure an invention agreement from the laborers on his staff.

3. Unless there is to be a fundamental change in our patent system, it is only the inventor who may apply for a patent. The wording of section 12 in S. 789, of section 7 in S. 1809 or of section 6 of S. 1899 should be revised to avoid any inference that the applicant for a patent can be anyone other than the inventor.

We urge the board to approve and adopt this report, in principle, so that our views may be presented with your sponsorship at the hearing to be held June 1 and 2 on all four of these bills.

Respectfully submitted.

ANDREW R. KLEIN, *Chairman.*

The above report on the action of the Philadelphia Patent Law Association concludes my statement on behalf of that organization. The balance of this statement will constitute views which I express purely as an individual.

I wish to congratulate each of the four Senators who have respectively sponsored the above-mentioned bills. Each of them has proposed a bill which prescribes a uniform, National Government patent policy. Such uniformity is highly desirable and long overdue. A uniform policy will go a long way toward creating order out of a situation which has been in a chaotic state for some 85 years.

While I do not believe that any of the four bills in itself contains provisions all of which will best serve the public interest, I do believe that some of them contain provisions which should be enacted into law at the earliest possible time. Actually, I am convinced that the public interest would best be served if a bill similar to H.R. 4482, which Congressman Toll introduced in the 88th Congress, were adopted. Such a bill would do more to promote the progress of the arts and sciences than any of the bills here under consideration, and would annually save the taxpayers many millions of dollars in administrative expenses which will be incurred if S. 789, S. 1809, or S. 1899 is adopted. Moreover, the Toll bill would also dispose of the problem concerning rights to inventions made by

Government employees, which will not be dealt with upon enactment of the bills now being considered by the Senate Patents Subcommittee. Until that problem is disposed of by statute, a truly uniform, national policy regarding rights to all inventions arising out of Government-subsidized research will not be achieved.

I recognize, however, that the political climate today is such that a bill like that of Congressman Toll's has little chance of being enacted. Accordingly, to be as constructive as possible, I would like to make the following general and specific recommendations with regard to the bills here under consideration.

First, as to S. 1047, I wish to urge its adoption in order to eliminate an inequity of long-standing that has unnecessarily caused great hardships to owners of patents on inventions made without any governmental assistance. Recognizing that there are times and circumstances when the Government must have the right to make use of even privately held patented inventions for purposes of national defense, it is unconscionable to permit the promiscuous use of the Government's right of eminent domain in cases where other measures may be taken which would not jeopardize the Nation's defenses. This bill will rectify that situation without any dilution of the Government's right to use whatever inventions are deemed essential to the defense effort. I have only one minor suggestion regarding the wording of the bill, and that is to change "a patent" to—an unexpired patent—on page 1, line 8. I believe the reason for this change should be self-evident.

Of the three remaining bills, I believe that S. 1809 comes closest to representing the kind of Government patent policy we should have. It contains many desirable provisions which parallel provisions set forth in the memorandum and statement on Government patent policy which former President John F. Kennedy promulgated on October 10, 1963. It adequately covers the situations which S. 1899 purports to take care of in the public interest, but does so with some of the flexibility that experience with administration of the Kennedy directive has shown to be preferred by Government administrators and contractors alike. A number of provisions in S. 789 deserve to be given serious consideration, and I will point out those which I feel would improve S. 1809. At the same time I will indicate those provisions in both S. 789 and S. 1809 which I believe should be revised or eliminated.

Referring now to S. 1809, the first item that should be amended is the definition of "made" in section 2(g). I am well aware of the origin of the concept and the reasons for not exempting inventions that have been constructively reduced to practice, but I have never been persuaded as to the merits thereof. If an invention has been conceived and legally completed before the contract was awarded, why penalize the contractor who chooses to give the Government the benefit of the invention in the solution of a research problem? To require otherwise might tempt contractors to avoid use of precontractual inventions not yet actually reduced to practice, in the performance of their contracts, particularly if the inventions appear to have important commercial significance. In the long run the public will be the loser by failing to get the benefit of the best possible solutions to research problems which may be known and available to the contractor.

The second item meriting amendment is the language in section 3(b)(5) on page 5, lines 5, 7, and 8. In line 5, before "after" insert "but only"; in line 7, replace "that" by "to determine whether"; and replace "not" by "unjustifiably failed to"; and in line 8, change "erted" to "ert". I note that section 3(b)(5)(a) provides for the issuance of licenses by the agency head to third parties if the contractor fails to bring the invention to the point of practical application. Such compulsory working requirements are in the public interest and I highly approve of them. However, it is noted that the terms and conditions of such licenses may vary from agency to agency and even from case to case within an agency. This may not be desirable. In fact, this possibility and other factors in the provisions of S. 1809 make me urge that there be included in that bill a provision like that of section 14 in S. 789 under which the Secretary of Commerce shall promulgate Government-wide regulations which can be supplemented for internal administration by each other Government agency. Such a provision will help to make the proposed uniform Government patent policy truly uniform.

The third item in S. 1809 which should be changed involves section 4. Actually, there are several points here which merit reconsideration. The concept of deferring the determinations called for in 4(b) at lines 7 and 8 of page 8, and in 4(c) at lines 19 and 20 of page 8, is fundamentally bad in principle

and will cause tremendous administrative difficulties. In fact, practically all the administrative and judicial procedures provided for in section 5 are believed to be unnecessary. They are fraught with serious problems and will cause great expense which could be avoided if the deferral of the determinations as now called for were to be eliminated. Such deferrals will constitute bad law in that they violate some elementary contract principles; namely, that the contracting parties should agree and get into their written contract as many of the conditions of the agreement as can be foreseen at the time the contract is negotiated. The settlement of the patent rights question at the time of negotiation should present no real difficulty, and will save all parties from embarrassing and troublesome arguments afterward.

If it is deemed desirable to have a provision whereby the Government could claim title to a particular invention which arose out of performance of a contract, as a result of new, unusual and compelling factors not visualized when the contract was executed, instead of the deferred determinations of section 4 it would be better to include the provisions of section 7(a) in S. 789.

If section 4 is retained, subsection (a)(2), should be revised as it is too broad and ambiguous. At most it should be limited to the production of items which may be required by Government law or regulation. Subsection (a)(3) also should be revised, if not eliminated, as I do not see how it will be possible to determine whether the acquisition of exclusive rights at the time of contracting might confer a dominant position on a contractor, when no invention has as yet been made which might establish such an advantage in the contractor.

If section 5 is retained, the fourth item meriting consideration involves two changes. In 5(a)(2)(C), at line 7 on page 10, change "question" to "questions", and after "whether" insert "(1)"; and at line 9 on page 10, change the period to a comma and thereafter insert "and (2) such action will best serve the public interest.". In 5(b), at line 16 on page 10, before "the" insert "and that such action will best serve the public interest,". I believe these changes will require no explanation.

The fifth item involves section 6(b). At line 11 on page 12, after "if" insert "shown to the satisfaction of the court to be".

The sixth item involves section 7. At line 22 on page 13, reference is made to the filing of patent applications by the "contractor". Since contractors normally cannot file applications, perhaps this word should be changed to "inventor".

The final section is S. 1809 on which I would like to comment as my seventh item is section 8 which deals with the administration of patent rights acquired by the United States. Before doing so, let me point out that I believe it to be basically unsound and unnecessary for the United States to acquire title to inventions of its contractors or its employees, and that a far better policy would be that provided for in the aforesaid Toll bill, H.R. 4282 (88th Cong.). That bill would leave title in the Government's contractors or employees, subject only to compulsory working provisions. However, being reconciled to the apparent inevitableness of a statute which will call for the Government's acquisition of title to many patents, I am in that event strongly in favor of sound provisions for vigorous administration of those rights with the primary objective of maximizing utilization of all inventions to which they pertain. By the same token, I am strongly opposed to the concept of dedication of such rights as provided for in section 3(a), lines 9–17 on page 5, of S. 789. Dedication may tend to destroy the opportunities affordable by exclusive licensing of Government-owned patent rights for promoting the utilization of inventions.

The provision in section 8 for the granting of exclusive, as well as nonexclusive, licenses is good. It is consistent with the basic precepts of the American patent system; namely, that the granting of the right to exclude others from the practice of a patented invention, for a limited period of time, may be the essential inducement for the investment of resources generally required to convert inventions into useful and acceptable products and processes. The authority vested in the agency head to request, and the Attorney General to take, the necessary action to protect and preserve the rights acquired by the Government is good. It should settle for all time the question whether the Government should and whether it has the right to sue for infringement of patents which it owns. The constitutionality of such a provision undoubtedly will be questioned, even challenged, but in my judgment it will be upheld as a proper Government function.

Although section 8(b) broadly applies to the following situation, I recommend that consideration be given to adding an additional proviso along the lines of

section 5(c) in S. 789. Then it would be mandatory upon the agency head to grant an exclusive license to the contractor responsible for making the invention if, within 3 years after title to it was acquired by the Government, no third party actually made use of the invention. I also favor adding to section 8(b) the provision of section 6 in S. 789 dealing with the voidability of the rights left with the contractor. This would put extra teeth into the provision now covered by section 3(b)(5)(a), and may have to be reconciled therewith. But the principle is good and should be adopted; it has many of the advantages of the compulsory working requirements of the aforementioned Toll bill, H.R. 4282 (88th Cong.).

Another provision of S. 789 which I favor adding to. S. 1809, either to section 8(b) or at some other suitable place in the latter bill, is the essence of the former bill's section 3 (e) and (f). Those sections permit the agency head to waive, in certain situations, any rights the Government otherwise might have to acquire title. They make for flexibility which may lead to greater utilization of the inventions in question.

S. 789 has a secton 9 which should also be considered for addition to S. 1809. That section adds to the rights and remedies conferred by 28 U.S.C. 1498 the right of a patent owner to have his claim for infringement by or for the Government determined by the head of the appropriate department or agency. Such a provision not only would alleviate the jam in the Court of Claims caused by suits over such claims, but along with the passage of S. 1047 should resolve many of the issues that have in recent years led to decisions by the Comptroller General of the United States which have caused anguish not only among Government contractors but Government administrative authorities as well.

In concluding, I will first revert to the suggestion made above that the essence of section 14 of S. 789 should be incorporated in S. 1809. This is the provision which would, in effect, establish a central administrative agency to carry out the provisions of the bill. Alternatively, a separate agency for that purpose, along the lines of that proposed in S. 1899, should be established. The important objective, regardless of how it is achieved, is to provide for uniform rules, uniform procedures, and uniform interpretations so that persons dealing with different departments or agencies, or branches thereof, will not find unpredictably different results from case to case. Hopefully, a body of published uniform principles, practices, procedures and decisions will in time become available so that an orderly process of administration will be the happy result. This will also help in the event judicial review of such administrative actions should become necessary.

As a final observaiton, I note that section 9 of S. 1809 requires semiannual reports to the Congress, a requirement which also appears in S. 789 and S. 1899. This is good. However, I would strongly recommend that there be added to the information which those reports are to contain factual data on the actual cost of every phase involved in the administration of the laws governing the new national patent policy. This will be important if the Congress is to be able to assess the true value of those laws in the future, weighing the cost of their administration against the possible losses to the taxpayer in terms of the Government's patent rights which allegedly are being given away today in the absence of such laws.

It is my understanding that the present average cost to the taxpayer, per patent application filed by the Government, has been conservatively estimated to be approximately $2,000. This is a direct cost which does not include overhead, but is presumed to cover such functions as liaison between the patent advisor and the inventor, followup of the contract to obtain invention reports, searches in the Patent Office, drafting of drawings, preparation, and prosecution of the application. In 1964 the total number of inventions made by Government contractors and employees was 11,000 according to reports understood to have been received by the Patent Advisory Panel of the Federal Council for Science and Technology. At $2,000 per case—and note that S. 1899, for example, calls for the filing of applications on all patentable inventions arising out of Government-subsidized research—this would cost the taxpayers at least $22 million per year. Promotion of the inventions to maximize their utilization involves more speculative costs. However, there may be a clue in the experience which NASA has had recently. It is understood that NASA devoted approximately $3½ million for such purposes in 1964, and NASA then had some 1,500 inventions available for public use. At that rate, promotion of the Government-

wide total of inventions might run about another $22 million or a total annual cost for the overall operation of the Government's patent policy program of about $44 million.

These costs will be bound to rise tremendously if the new policy brings about the acquisition by the Government of title to many more thousands of inventions each year, as is to be expected. As a taxpayer, I think that in view of these estimates it would be highly desirable for the Congress to obtain accurate reports on the actual costs each year, so that a realistic reappraisal of the value of any law resulting from the bills here under consideration can then be made.

APPENDIX

STATEMENTS BY HOWARD I. FORMAN

Following is a list of publications by Howard I. Forman, B.S. (chemistry), LL.B., M.A., Ph. D., dealing with the subject of Government Patent Policy:

1. "Government Ownership of Patents and the Administration Thereof" (27 Temp. L. Q. 31 (1954)).
2. "Patents—Their Ownership and Administration by the U.S. Government (Central Book Co., New Yorfl 1957).
3. "Federal Employee Invention Rights—What Kind of Legislation?" (40 J. Pat. Off. Society 468 (July 1958)).
4. "Wanted: A Definitive Government Patent Policy, (3 PTC J. Res. & Ed. 399 (winter, 1959), reprinted in Forman, ed., Patents, Research and Management, 509 (Central Book Co., New York, 1961)).
5. "Forgive My Enemies for They Know Not What They Do," (44 J. Pat. Off. Society 274 (1962)).
6. "Impact of Government Patent Policies on the Economy and the American Patent System, "(Patent Procurement and Exploitation, 181 (Bureau of National Affairs, Washington, D.C., 1963)).
7. "Government Ownership and Administration of Patents," (Calvert, ed., "The Encyclopaedia of Patent Practice and Management," 360 (Reinhold Publishing Corp., New York, 1964)).
8. "President's Statement of Government Patent Policy: A Springboard for Legislative Action," (25 Fed. B. J. 4 (winter, 1965)).

STATEMENT OF HOWARD I. FORMAN, PRESIDENT, THE PHILADELPHIA PATENT LAW ASSOCIATION

Mr. FORMAN. My formal written statement more completely identifies my background of experience. But briefly today I would like to say I am a patent attorney and political scientist living and practicing in Philadelphia. I appear here today in a dual capacity—first as president of the Philadelphia Patent Law Association and secondly as a private individual.

The formal written statement which, Mr. Chairman, you have agreed to have incorporated in the record, contains a statement by the board of governors of our association regarding S. 789, S. 1047, S. 1809, and S. 1899, together with the report and recommendations concerning those bills by our association's committee on Government patent policy.

To conserve time I will read only a portion of the statement of the board of governors.

They "earnestly commend the terms of Senate bill 1047 which would bring to an end the unauthorized taking of patent rights by the Government except when national security requires."

They "also earnestly commend the provisions of Senate bill 789 and 1809, but not in the precise form presently proposed."

Rather, "they very greatly hope that these two measures might be consolidated and then streamlined in accordance with the accompanying recommendations of our committee on Government patent policy.

If such a consolidation could be effected, the resulting system would be flexible enough to permit accommodation to widely varying circumstances.

"On the other hand, it is our view that S. 1899 is unduly rigid in its terms, and that it would provide a less effective means for stimulating real advancement, since it would increase the number of instances in which the patent would be owned by the Government and would therefore afford no real protection to a licensee."

That is the end of that formal statement.

The rest will consist purely of my personal views.

In my formal statement I indicated at some length and in some detail my reasons for favoring adoption of S. 1047 and for believing that, of the three remaining bills, S. 1809 comes closest to representing the kind of Government policy we should have.

I made some specific suggestions for amending S. 1809 in some instances by adopting provisions set forth in S. 789. But I will not go into them now, for I trust that the subcommittee and its technical staff will glean them from the written statement and can best weigh the merits of the respective suggestions upon making such a review.

Mr. Chairman, only a few weeks ago, on June 18 to be specific, I delivered a talk entitled "Government Patent Policy in the United States" at the Ninth Annual Public Conference of The George Washington University Patent, Trademark, and Copyright Research Institute. I sent copies of that talk to you, Senator McClellan, to Senator Burdick, to Senator Hart, and to your subcommittee's chief counsel, Mr. Brennan. I requested then, and I would like to request now that that paper be incorporated as a part of my testimony before this subcommittee and I hope you will consider this favorably.

Senator McCLELLAN. It may be received and published in the record.

(The document referred to follows:)

GOVERNMENT PATENT POLICY IN THE UNITED STATES

(By Howard I. Forman)

Presented on June 18, 1965 at the Ninth Annual Public Conference, The Patent, Trademark, Copyright Research Institute, The George Washington University, Washington, D.C.

NOTE.—The views herein expressed are entirely and solely the responsibility of the author, and they do not necessarily reflect the views of his employer or of any other organization with which he has been or many currently be associated.

Mr. Chairman, distinguished guests, ladies and gentlemen: The 175th anniversary we are celebrating today is of the act of 1790 which established the U.S. patent system. It is interesting to note that it was almost 75 years after that notable beginning, on June 3, 1864, to be exact, when a law was enacted which authorized the Government to take title to patents as an incident to certain infringement suits. Perhaps that date could be considered the beginning of all the ruckus we hear today about Government patent policy, in which case it's now over 100 years and still not settled.

Actually, I prefer to consider the act of 1883 as the starting point, for it was in that year that Congress decided to authorize the executive branch to obtain patents on inventions of its employees, without charging the applicants any fee for filing the application, in return for a nonexclusive, royalty-free license to the United States. In that event, the abortive attempts to establish a uniform Federal patent policy only go back a little over 80 years. During most of that time each Government agency established its own practices and procedures, some with and some without any stated policy. Although many

bills or resolutions have been introduced in Congress seeking to establish a uniform patent policy for all Government departments and agencies, none has been passed to date.

I will not attempt to explain the reasons why so many bills have been introduced, why only a few were passed which established patent policies for a few agencies, and why we have been between 80 and 100 years in the process of arriving at a uniform Government patent policy. At least 2,000 printed pages of such explanations have been published to try to tell this story, and that's just counting the 3-volume, 1,000-page report of the U.S. Attorney General which appeared in 1947, my own book published in 1957 and 7 law review articles I have written since then which altogether totaled some 600 pages, the 100 or so pages of the dozen monographs published by the Senate Patents Subcommittee in the past 10 years, the more than 200 pages which have been devoted to the subject by the journal of the George Washington University's Patent, Trademark, and Copyright Research Institute, and some 100 pages of symposia in the Federal Bar Journal. I just don't have the time this morning to discuss the facts represented by all that material.

In view of the relatively short time I have in which to cover so much ground, I'd like to get right down to cases and review the situation as it exists today. Nothing could be more timely for, at this very moment, Congress appears much closer than it ever has been to the brink of passing some sort of uniform Government patent policy legislation. I'd like to try and boil down the issues for you, consider some of the suggested solutions, and perhaps make a point or two of my own.

Our Government currently is spending at the rate of $15 billion per year on research and development. As an incidence of this work thousands of inventions are expected to be made and in fact are being made. Some of these inventions may have great potential of various kinds. Apart from their being useful in solving actual problems which the Government has in connection with its conduct of the Nation's defenses, development of our agriculture, and the improvement of our general health and welfare, the inventions may be important to the public in many other ways.

With the aid of these inventions the people may reap a whole harvest of new and better things with which to improve their way of life if some of those inventions are developed for commercial utilization. New plants may be built, new industries may spring up, employment may be given to countless thousands, and many more derivative benefits may result from these new developments. Assuming that this will be done by private interests rather than by the Government, entrepeneurs who invest in the development of these new products, who build the plants, hire and manage the people, and purchase the equipment for them to use, will also stand a good chance of profiting on their investment if their efforts prove successful.

There is one slight catch to all this, however. Inventions are peculiar things in that their very newness almost always connotes a sense of incompleteness or imperfection, like diamonds in the rough. Rarely are new inventions so simple and so complete that, with very little morey or effort, they can be rapidly readied for the market and quickly meet with commercial acceptance. More often than not, the inventions will have to undergo extensive developmental or product engineering, and this postinventive developmental phase may take tens and hundreds of thousands of dollars, perhaps even many millions of dollars.

This might not be a bothersome problem if each such investment carried with it some assurance of success. But the developments frequently may not turn out as expected; the products may not "catch on" with the public, etc. The expenditures in such cases may be so prohibitive as to discourage many people from such undertakings unless there was someway of guaranteeing a reasonable chance of success. At the very least, the guarantee should provide that when the new products or processes are fully perfected the one who took all the risks would have a period of time within which to try and recoup his investment, or at least a reasonable share thereof, before having to face the merciless onslaught of open-market competition from imitators who, having made no such expenditures for research and development, generally can sell at much lower prices. As a rule, the only way such assurances can be given is under the operation of our patent system. If the inventions are patentable, and if a prospective developer can be given the right to exclude others from practicing the invention for a limited period of time, the risks can be balanced against the thus enhanced prospects of investment recoupment, and the would-be entrepreneur can be more readily convinced to apply his capital, skills, and energies to such a development.

If we are interested in having as many of such inventions developed for commercial utilization as we possibly can, commonsense would seem to suggest that in those cases where the grant of such exclusive rights is a prerequisite to inducing entrepreneurs to tackle the developments we should try our best to make such grants available to them. If this were considered to be in the public interest there would, of course, still be certain other problems to consider. One is who should own the patent rights at the outset; The Government? The Government contractors? The Government employees? If it is the Government, the next problem is to determine the basis on which the Government should grant rights under those patents to a potential developer of the inventions in question. Such a determination can cause many political problems. Allegations of favoritism will be among the milder forms of criticism, and more such unpleasantries will be bound to occur. On the other hand, if it is decided to leave title with the Government's employees or contractors other questions must arise. Mainly they will concern the equities involved in the Government's forfeiture of claims to potentially valuable rights which, at first blush, would appear to belong to the Government (and hence to the taxpayers) since the inventions arose out of research and development which were at least in part paid for out of public funds.

Until very recently, in considering the complex problems involved in determining a satisfactory Government patent policy, few people gave much thought to the inventions themselves. The inventions were just pawns in a political chess game. Almost no one seemed to care whether it was important, in the public interest, that as many as possible of the inventions in question should be developed for commercial utilization. Certain minority, but outspoken, factions in both the executive and legislative branches of the Government have demanded that it should take title to the inventions on the theory that Federal funds paid for the research from which the inventions were spawned, and the Government therefore should be entitled to receive all the fruits thereof, including full rights to all the inventions. In brief, they have said, the taxpayer should not be made to pay twice for the same inventions, once in the form of public funds for research and development contracts or salaries, and again in the form of royalties when the inventions are sold or licensed to a commercial operator.

What would happen to the inventions themselves after the Government took title? Several alternatives have been suggested. One is that the inventions should be placed in the public domain by publication and dedication. Another is that the Government would take out patents on the inventions and then license anyone on a nonexclusive basis, with or without a relatively modest royalty. Only recently has it been suggested that in some select cases the Government might find it desirable to license on an exclusive basis, again with or without the payment of a royalty, with the definite requirement that the licensee give evidence that it has brought the invention to the point of commercial acceptance in a stipulated period of time, or else forfeit the license. In some special few instances it has been proposed that the Government might undertake to manufacture important inventions itself, rather than chance their going undeveloped because private interests did not find them sufficiently attractive or too hazardous to tackle on their own.

Note that in all of these suggestions a principal objective is the utilization of the inventions. They differ from each other only in their methods of accomplishment. In effect, under one extreme the inventions would be completely outside the patent system, with no inducement to manufacturers in the form of advantages inherent in the right to operate on an exclusive basis for a limited period of time. At the other extreme, the inventions would be subjected to the protection afforded by the patent system, and the promoters of the inventions would have the help of a headstart over their competitors.

I do not mean to suggest that only inventions which are covered by patents, and which are exclusively licensed, will attract manufacturers and developers. There are, of course, numerous instances where the potential market is so enormous, the required investment for development relatively so small, and the risks of failure so limited, that many entrepreneurs will be attracted to practice inventions without the benefit of any exclusive rights. But the chances obviously are much greater that, if given some headstart or leadtime as can be done by exclusive patent rights, in many situations inventions will be manufactured which otherwise might remain completely unattractive to would-be manufacturers. I don't have to illustrate this point for you by examples. Just ask yourselves the question: Wouldn't you be more inclined to invest $10,000, or $100,000, or $1 million in the development of a new invention if you felt that you would have a fair chance to fight off imitators who are intent on pricing you out of the market

by copying your invention as soon as it is introduced into commerce? Wouldn't you feel it is only reasonable to have some protection against such imitators until you had gotten back some of your investment, and perhaps had "sold" the public on the merits of your invention before some cheap imitators might sour the consumer by putting out copies of your invention that won't work or last very long?

Yesterday, Dr. Hershey told how the Du Pont Co. felt about the importance of having a sound patent position before investing $1 million or sometimes $50 to $60 million in a new development. If a company of Du Pont's resources and preeminince in its field finds it must rely on patents, it should be obvious that a small concern or independent inventor needs that protection far more.

Some years ago the late Circuit Court Judge Jerome Frank, in commenting upon the then current abuses of the American patent system and the need for legislative reform to eliminate the opportunity for misusing patents, stated: "* * * but we must be careful not to throw out the baby with the bath water."

Likening the patent system or patents to a baby calls to mind the Biblical story of King Solomon who was obliged to decide which of two wailing women, both of whom claimed to be the mother of an infant child, was the real mother. You'll recall he declared that, since he found it impossible to determine to whom the child rightfully belonged, he would be cut in two and give each woman a half. One of the women said that would be satisfactory to her, but the other said, "Oh no, my king, give her the child." Solomon then realized that the latter was the real mother, for she preferred to give up the child rather than permit it to be slain, and he awarded the child to her. In a similar way the controversy over who should own rights to inventions and patents arising out of Government-supported research and development makes one wonder if we don't need a modern-day Solomon to pull the same sort of stunt all over again.

Too many people in Government circles are concerning themselves with the possibility of "giveaways" of patent rights to Government contractors. Believing that they are protecting the public interest, they are claiming that the public is the true "mother" or owner of the child (the "child" in this case being the patent rights arising out of Government contracts), and they want to cut up the child and hand over parts of it to as many people who want to claim a share. How much better to help the child grow to maturity, and to let the real "mother"—the public—share in the benefits of such fully developed children who can then make contributions of their own to the benefit of mankind.

According to the National Science Foundation, the Government now is putting up about 70 percent of all funds expended annually for research and development in this country. For the sake of discussion, let us assume that the proportion of dollars spent for research can be roughly correlated with the number of patentable inventions which arise out of the research. Let us further assume, in order to keep the numbers small enough for easy contemplation, that every year the total number of patentable inventions made in this country is 1,000. This would mean that each year approximately 700 out of 1,000 patentable inventions would be subject to whatever decisions are made with regard to the Government's patent policy. You can surely see that the way we handle those inventions will become mighty important to the progress and future of this country when you consider that the products of the inventive genius of this country are not unlimited. They are national assets which must be conserved and nurtured just like our timber reserves and our farmlands. We cannot afford to let them become decayed or eroded through lack of use. We must try and utilize as many of them as we possibly can.

Those of you who have been intimately involved, or for other reasons have followed the great debates over Government patent policy in the past decade, probably are wondering why I haven't as yet said a word about the relative merits of the propositions that the Government should or should not take title to the inventions in question. Quite frankly, I have left that issue for last because it's the more complex one to deal with, and the one which is far more difficult to resolve to everyone's satisfaction. It's the issue that invariably brings up heated arguments, generally charged with emotionalism and not quite as much lucidity. What's more, in my humble judgment, it's the least important factor to consider from the public interest point of view. If we could all agree that, from the viewpoint of the Nation's welfare, it is more important to figure out how to maximize the utilization of the inventions than it is to worry about who should own the rights to them, I believe we would agree much more readily and

universally as to who should own title to the inventions, and whether any conditions should be attached to such ownership.

The sophisticates among you in this field of Government patent policy know the arguments which have been advanced by the Governments' contractors as to why they should be allowed to keep title. The main one is that the contractors usually sought by the Government are those who have had a good deal of background know-how in a given area of technology. They probably have had years of experience, and have plants, facilities, personnel, all of which were assembled with private investment. As a rule, they can be expected to solve the Government's research problems with the best possible solutions, in the shortest period of time, and therefore with the least possible cost to the Government. Inventions which may arise out of their contractual operations can be expected to be the product of their background know-how as well as of any advance in the art, or foreground developments, which they may chance to make in the course of working on the Government's assigned problems.

It will generally be impossible to determine how much of the background and how much of the foreground developmental efforts went into the making of the inventions. Whether considered in terms of cash, personnel time, facilities, or know-how, if the amount of investment by either the Government or the contractor is to be the basis for determining the respective equities in the inventions, the baby-dividing decision that King Solomon had to make becomes a single one by comparison. Obivously every contract situation will be different from every other one, and the equities may range from zero percent investment of background developments by the contractors in some instances, to perhaps 90 percent or more in others.

Apart from the obvious problems inherent in attempting to balance such nebulous equities, there are numerous other problems to be considered which I have time only to mention briefly. For example, the incentive of the contractors to report all inventions willingly and fully is bound to be less when the contractor does not keep title to them. If the Government takes title, there still is the job of evaluating the inventions, patenting them, deciding whether or not to license them, who to license, how to license, etc. Finding extremely hard to get patent and other technical personnel to review the contract records to make certain all inventions are reported, to evaluate them, to prepare and prosecute applications covering them will be a serious problem.

The cost of doing all this is a factor which should be given serious consideration. It has been suggested that to leave the rights to inventions with contractors is to give away benefits that belong to all the taxpayers. No one will be able to place a dollar value on that alleged giveaway, because no one can ever tell what the intrinsic value of such inventions are when they have not yet been developed for the marketplace, and the costs of such development and the ultimate price which the consumer is willing to pay for them have yet to be determined. But one can estimate with some reasonable accuracy just how much the taxpayer will pay in actual cash if the Government proceeds to take title to all inventions arising out of its contracts.

I have been advised that some Government agencies calculate their present average cost of evaluating, filing, and prosecuting a patent application to be $2,000. This is a direct cost which does not include overhead, but is presumed to cover such functions as liaison between the patent adviser and the inventor, followup of the contracts to obtain invention reports, searches in the Patent Office, drafting of drawings, preparation and prosecution of the application. In 1964 there were 11,000 inventions made by Government contractors and employees, according to the Patent Advisory Panel of the Federal Council for Science and Technology. At $2,000 per case, this would amount to some $22 million per year.

If promotion of these inventions to maximize their utilization is undertaken, the costs will increase by at least that same amount. In 1964 the National Aeronautics and Space Administration devoted some $3½ million to promote some 1,500 inventions available for public use. At that rate, promotion of the Government-wide total of patents would run to $22 million. Thus the total bill, under the current practices of most Government agencies according to which title is taken only in a relatively small percentage of cases, would be over $44 million. If the legislation now pending on Congress should cause a sharp increase in the number of cases to which title is taken by the Government, probably amounting to many more thousands of inventions, the taxpayer will be paying on the order of perhaps $100 million or more each year for these programs.

Compared with such real, measurable expenditures, the so-called giveaways of nebulous patent rights might turn out to be so-called "chicken feed" by comparison. In a statement which I submitted to the Senate Patents Subcommitee 2 weeks ago, I suggested that if any bill is to be enacted which plans to take title to many inventions and patents, as has been proposed, it would be desirable to have that law require an annual report to the Congress of each and every cost of administering that program. Then, in years to come, Congress can have some factual data on which to decide to continue or terminate the program.

Now, for some final and concrete observations. After a decade or so in which the whole matter has been gathering momentum in the Congress, the issue of a Government-wide, uniform national patent policy appears finally to have reached the decisionmaking point. Three bills in the 89th Congress at the present time are the focal points of this attention. Two of them are so close together in principle, namely Senator Saltonstall's S. 789 and Senator McClellan's S. 1809, they may be considered as representing the same general approach to the problem. The other one, S. 1899, introduced by Senator Long, of Louisiana, represents quite a different approach.

The McClellan and Saltonstall bills rather closely parallel a memo and statement on Government patent policy which former President John F. Kennedy issued on October 10, 1963. That directive, incidentally, currently is being followed by all Government departments and agencies which are not by statute bound to follow some other patent policy. These two bills, and the executive branch directive, incidentally, seem to be winning support and indorsement from most of the industrial and patent bar groups which testified at Senate Patent Subcommittee hearings held earlier this month. In essence, all three tend to leave title with Government contractors except in certain specified situations, e.g., where the field of research is a new one to the contractor and the Government has made or is making substantially all the financial investment involved, where the research is in the public health or welfare areas, where the contract is to develop or improve things intended for use by the general public, or where the contractor is to operate a Government-owned facility. Provisions are made for compelling the contractors who are permitted to retain title to bring the inventions to the point of practical application. Failure to do so may result in the voiding of rights given to the contractors or their being obliged to grant licenses to others to practice the inventions. Thus, by either compulsory working or compulsory licensing provisions, the present Kennedy directive and the proposed McClellan and Saltonstall bills are aimed at promoting utilization of the inventions to which the Government does not claim title. As to those inventions whose title is claimed by the Government, either exclusive or nonexclusive licenses may be granted under specified circumstances.

The Kennedy, McClellan, and Saltonstall approaches to the problem of settlement of the Government patent policy controversy are as close to being in the true public interest as any bill or regulation can be, and yet stand a reasonable chance of being enacted into law in the present political climate. Their only drawback is that, in attempting to resolve the so-called equities between the Government and the contractors, instead of providing for Solomons they are establishing Shylocks. In those cases where the Government's procurement officers are going to have to determine when to take title and when not they will be plagued to the awful responsibility of exacting just one pound of patent "flesh," no more and no less. Of course, if a contractor feels he has been made to bleed there are provisions for administrative or judicial review, and this might solve such problems in the best Shakespearean traditions.

The Long bill is essentially a title-in-the-Government approach, with practically no exceptions. Senator Long, unfortunately, has been completely sold on the notion that leaving any patent rights with contractors is sheer folly. For years he could only see them getting richer and bigger and stronger, as they are permitted to accumulate patent rights on inventions arising out of Government's contracts, and he decried the fact that this tends to make them more and more monopolistic. Only recently has he given consideration to the utilization of inventions which the Government would acquire by his current legislative proposal, and provision is made for licensing them, with or without royalties, under such terms as would be established by the administrator of any agency newly established for the purpose. In the long run, it is submitted, this type of

legislation will not be in the true public interest for it will do far less to promote the utilization of inventions than will the McClellan, Saltonstall, and Kennedy approaches that encourage the original inventors or assignee-contractors to develop the inventions which their expertise helped to originate.

Although I do not believe that Senator Long's approach is in the public interest, I do believe that Senator Long has done this Nation a great service by carrying on a relentless and effective campaign to enact legislation which will embody his concepts of a uniform Government patent policy. Without his efforts there undoubtedly would not have been created the issues which spurred President Kennedy to issue his directive. His piecemeal legislative efforts, by which he has succeeded in tacking on Government patent-rights-title-taking-amendments to several bills that have become law in the past few years, undoubtedly will prod the Senate to acting on whatever bills on the subject of a Government-wide uniform patent policy Senator McClellan's Subcommittee on Patents and its parent Judiciary Committee reports to the full Senate. At the same time, credit must be given to Senator McClellan for his painstaking efforts in resisting the hurried and harried piecemeal legislative approach, and his patient sifting of testimony and evidence in the quest of an acceptable Government-wide law. In this effort, of course, he is being aided by the considered interest and support of a number of members of his subcommittee. Only 2 weeks ago, incidentally, Senator McClellan successfully led a battle on the Senate floor to prevent adoption of Senator Long's amendment in connection with a vital NASA appropriations bill. In the course of that debate, by the way, several Senators vowed to do their utmost to promote the passage of a uniform Federal patent policy bill this year.

My one lament at the moment is that all the legislative proposals which purport to establish a uniform patent policy for the Government have omitted any reference to patent rights on inventions made by Government employees. They are currently being administered by the Patent Office pursuant to an executive order, in a more or less secretive manner, and apparently will continue to be so unless Congress does something about them too. If maximizing utilization of inventions arising out of Government-sponsored research is to be an objective of any legislation in the interest of giving the public the advantages of as many as possible of the inventions developed under the inducement of the benefits of the patent system, shouldn't this also apply to inventions of Government employees? Certainly, a truly uniform, national policy regarding rights to all inventions arising out of Government-subsidized research will not be achieved until the problem of those inventions is also disposed of by statute. Those inventions should not be treated like unwanted orphans; they are just as much a part of our national assets as inventions made by Government contractors.

In concluding, I will observe that it must be apparent that this whole area of Government patent policy is a difficult matter. It is confusing to people who cannot consider it from a broad philosophical outlook such as I have outlined for you this morning. I will cite one instance of such confusion that arises when almost any aspect of this subject is discussed. On April 8, I was privileged to serve as moderator of the symposium which opened the 175th anniversary of the patent system at the Sheraton-Park, here, in Washington. One of the three distinguished persons who spoke that morning was an internationally known labor leader whom I greatly admire and respect for his tremendous achievements in many fields of human relations and public welfare. In discussing our patent system he pointed to many of its faults which prevent inventors as a whole from obtaining greater rewards for the products of their "blood, sweat, and tears." He had my complete sympathy there. But then he went on to indorse Senator Long's view that, in the field of Government contracts for research and development, inventions and patents obtained at public expense are being given away with little regard for the economic and social consequences. His recommendation was that all patents developed at public expense should be put in the public domain. What he failed to appreciate, of course, was that if this were done there would then be no way of getting for the inventors a share of the profits or other proceeds which he was advocating they should have. In other words, he was suggesting that we should kill the goose that lays the very golden eggs which he wanted to have shared. Or was he in favor of cutting up the child because he was unhappy with the manner in which its "mother" was being determined? Shades of King Solomon, or should I say Senator McClellan?

Mr. FORMAN. I believe that the prepared statement which I submitted prior to June 1 and the talk I just referred to amply set forth my general views on Federal patent policy and my specific views on the bills you are considering here today.

I would like now to dwell only on the main reasons why I believe legislation of the kind embodied in S. 1809 comes closer to being in the public interest than any of the others, and why S. 1899 is the furthest of the three bills from being in the public interest.

The proponents of legislation represented by S. 1899 make these three principal claims:

1. The public should not have to pay a second time through royalties or higher prices for inventions which arose out of research and development which was at least in part paid for out of Government funds.

2. Numerous Government-originated unpatented technological advancements have been used by industry. Hence, the argument that a patent is a necessary inducement to development of inventions for commerce by industry is invalid.

3. Leaving patents in the hands of Government contractors only tends to increase the size and wealth of large corporations making them more monopolistic, more and more culpable of antitrust violations, and more likely to adversely affect small business.

My answer to these claims follows:

I believe that if the public could be given the whole story, without the headline hunting labels such as "Billion-dollar giveaways," the average person would agree with me.

With respect to the first point—in the long run this country and all of its people stand to benefit far more if more and more inventions are utilized—that is, made available for use by everyone—than if they are allowed to lie fallow because no one wanted to take the risks of investing in their development.

I, for one, would gladly pay an extra premium in royalties or higher prices in order to get the benefit of a new laborsaving device or possibly a lifesaving invention, or something which increased my standard of living. I would much rather get those benefits even if my taxes did help pay for the inventions than to run the risk of not having them at all.

Gentlemen, would you object to such so-called double payments if they resulted in the development of a cure for cancer or even if it just doubled the mileage you could get on a gallon of gasoline in your automobile, especially when you realize that under our patent system, after a stated number of years the invention will be in the public domain.

I know I would certainly not object at all.

I would like to point out an illustration I have repeated many times before many groups to show what I think is the real issue here, or at least one of the major issues.

Our technological inventive ability in this country is necessarily limited. There are only so many inventions that can be made in a given year. For simplicity's sake, I like to consider this in simple round numbers.

We can make, let's say, a maximum of 1,000 patentable inventions in a year, 70 percent——

Senator McCLELLAN. What do you mean make a thousand inventions? Who knows how many inventions may come this year and how many next?

Mr. FORMAN. We do not know, Senator, of course. This is merely a simplified hypothetical illustration to explain a point.

Senator McCLELLAN. All right.

Mr. FORMAN. Let us say that in any given year only 1,000 inventions are made in this country. They constitute the total productivity of the inventive genius of the entire Nation. These inventions are national assests. What we do with them may determine the country's future. They certainly will determine the progress of the country, and maybe even determine the existence of the country itself.

Now, if 70 percent of all the money spent in the United States for research and development goes into Government contracts—and if we roughly correlate this in terms of numbers of inventions—this could mean that the future benefits to our Nation from 70 percent or 700 out of the thousand inventions are going to be resolved when you settle this question of Government patent policy.

Now, how many of those 700 inventions can we afford to let go down the drain because no one wishes to undertake their development? We never know but that one of those inventions might be the cure for cancer; or it might be the means for the causing establishment of a new industry; or it might be the answer to some national defense requirement. Because we never know it is important that we do whatever we can to develop every one of those inventions that we can possibly utilize—and not just be satisfied with a "paper" invention.

With regard to point two, of course, patents are not necessary inducements for the development of all inventions. Industry constantly brings to the marketplace relatively simple, unpatentable inventions for which there is much demand. When there is very little investment required, there is no great worry about competitive risks and no concern over the likelihood of imitators coming out with cheap imitations after an expensive investment has been made in research and development by someone else.

Now, if the Government wishes to finance all the risk taking research and development work in its own laboratories, as when the Department of Agriculture makes a new plasticizer out of an epoxidized oil, or develops a new dialdhyde starch, it is a simple problem to find manufacturers for those kind of products. Such situations only prove how important it is for the manufacturer who has to invest his own money to develop an invention to have it protected by patents.

There are always people who are ready to imitate after the developmental risks are no longer a factor.

The real difficulty is in finding manufacturers who will undertake to develop an invention when the research and development is expensive and the risks of success are extremely great.

Now, I would like to cite an actual case history which I not only know about—I was actually involved in the negotiations which I shall

describe. I filed the full case history with the chief counsel for this subcommittee.

This involved an invention which concerns the saving of life. It had to do with extending the shelf life of blood bank blood. This is the blood that the Red Cross and other agencies gather and then put on a shelf. It goes bad in 21 days under normal circumstances. You normally cannot prolong its useful life as whole blood.

In the case of open heart surgery, in the case of situations where you are trying to get blood to the far corners of the world, 21 days often is not enough. It is important if you can extend the life of that blood by another week, another month, or longer, because blood is a commodity you just cannot get any time you want it.

Now, the Jefferson Medical College of Philadelphia had some surgeons who were interested in trying to develop a way of extending that blood life, they received some grants from NIH, and they tried to do this job. They found themselves at an impasse. They could not solve the problem. They had come up to a point and they found out that they were not getting over the hump.

They went looking for somebody outside, an expert who could help them. They found such a man, an experienced ion exchange chemist known the world over. He happened to be there in Philadelphia working for the company where I happen to be employed. He was asked if he would help. His services were volunteered gratuitously and many thousands of dollars of his time and materials were given to the institution. Eventually, the problem was solved, an invention happened to be made, and the invention has proved to be patentable. The question is—Will this invention get out into the public? Will this invention be developed for use by people all over the country? It has worked in the laboratory, and the technical people have reached the point where they think and know it will be useful for saving human lives. But there are considerable risks in the development. Nobody can guarantee that this invention, when tried out in mass production, is going to work successfully.

The Jefferson Medical College and our company, both of which have had no background, incidentally, in developing this type of invention, went looking for somebody who had the experience and the interest. We found only five laboratories in the country, five commercial companies, that had the required background of experience. They all decided it was too great a risk to get into. Only one of them decided to take the chance and that was Baxter Laboratories, of Morton Grove, Ill.

Senator McCLELLAN. Well, now, they have the exclusive right to it?

Mr. FORMAN. No, sir—I have not come to that. If I may, I will bring it out in just a moment.

Senator McCLELLAN. All right. I will be patient.

Mr. FORMAN. Baxter said they were interested, but they made some computations and figured it would take a million and a half dollars to bring it from the point where it was at Jefferson Laboratories to the point where they could put it in the hands of physicians and surgeons throughout the country.

They asked what the patent situation was. We went down to NIH to try to straighten this question out, because under the grant Jeffer-

son could keep the rights, provided they had a patent policy of their own whereby they would exploit the patented inventions. This is the general policy in connection with such grants.

But when it was pointed out that our company, because of its employee, had also been a participant, a joint inventor here, the question was raised, Would we yield our rights, or how else should the situation be handled? They did not know because they apparently had never dealt with that kind of situation, and there was no provision in the Department of Health, Education, and Welfare regulations which covered it.

We had some discussions with the Surgeon General and finally it was pointed out that, under the October 10, 1963, memo and statement of the President on Government patent policy—which stresses the desirability of utilizing all inventions in the public interest at every possible opportunity—it was for the good of all, in the public interest, to get this invention out of the laboratory and do everything that could be done to make it available to the public. They agreed—they said all right, finally—"We will agree to permit Jefferson to grant a 5-year exclusive period to develop this invention—5 years from the time that the Food and Drug Administration and the Division of Biological Standards approve this invention for public use." This much time, it had been estimated by Baxter, would give them a chance to recoup about 30 percent of that million-and-a-half-dollar investment. They figured that they would take their chances on recouping the rest of the investment and making a profit on it in the nonexclusive period after the exclusive period expired, relying on their "leadtime" to put them in a competitive position.

Incidentally, I ought to point out that the grant was for about $15,000 and our company invested about an equal amount, $10,000 or $15,000 at that point—or a total of about $30,000. As Dr. Price pointed out earlier this morning, relatively small sums generally are needed to make a given invention. But, as in this case, a million and a half dollars would be required to reduce that invention to the point where it could be used by the public.

Baxter agreed to accept the license with the 5-year exclusive period. Then the Department of Health, Education, and Welfare decided that this was not sufficient. They said—it is all right to give a 5-year exclusive and then say it will be opened up nonexclusively to any other manufacturer who wants to make this later—"But suppose, Baxter, you use some of your background inventions that you had before you start work on this development, or suppose you use some new ideas that you make in the course of investing your $1½ million—these inventions might be desirable or necessary to the production of the end product of your development that is acceptable for the commercial market. Without these added ideas, what good will a nonexclusive license be to a potential second or third producer after your exclusive period ends? We would like you to yield those rights to the public, too."

Well, this was asking Baxter to give up its commercial birthright. It may have spent many millions before on some of the ideas that they had in their own research department. Besides the $1½ million they were planning to spend to reduce the invention to a practical embodi-

ment was their own money. Why should they share rights to inventions which may be made through research done entirely at their own expense?

Well, after 2 years of arguing up and back, Baxter finally said they could not afford to take the risk under the supplemental conditions imposed by the Department of Health, Education, and Welfare and they withdrew.

I might point out that this example well illustrates how important it is to give developers of inventions the inducement of protection against cutthroat competition for at least a limited period of time in order to get people to take on the development of inventions which involve great risks as to the chances of success.

Senator McCLELLAN. Now, if I understand you, in that instance—what was the name of the company?

Mr. FORMAN. Baxter Laboratories.

Senator McCLELLAN. They finally agreed that they would undertake it for a 5-year exclusive right?

Mr. FORMAN. Yes, sir.

Senator McCLELLAN. But then the question arose if there were any, I would call them, byproduct inventions, fallout inventions or discoveries, who would get those? And the Public Health Service wanted—the Surgeon General—wanted Baxter to agree that the Government should have those.

Mr. FORMAN. No, sir. They wanted the equivalent of that, but technically it worked out a little differently. They merely wanted Baxter to agree that it would provide nonexclusive licenses to anyone who decided later to make the final development, the final invention.

Senator McCLELLAN. And they were never able to get an agreement?

Mr. FORMAN. That is right.

Senator McCLELLAN. Now, what has happened? Is the product being used now?

Mr. FORMAN. Not yet.

Senator McCLELLAN. Oh, is it still not on the market?

Mr. FORMAN. It is not on the market, but we expect that it will be, and for this reason.

Our own company, having gone as far as it had with its gratuitous contributions to the making of the invention, and fortuitously having acquired a small pharmaceutical manufacturing company—just prior to Baxter's withdrawal—decided that it would try to carry on the work for a while rather than let it die, and this work has actually been going on there ever since.

But we went back to the Surgeon General to explain the situation, and he very cooperatively reconsidered the problem. We pointed out that, like Baxter, we could not afford to invest that kind of money since this is a very perilous type of invention, and there can be no guarantee it is going to work or that it will be accepted by the medical profession when it is placed on the market, and they withdrew the supplemental requirements that they had imposed the year before.

Senator McCLELLAN. On Baxter?

Mr. FORMAN. Yes, sir. And the way it now stands, it is merely on the basis that the invention will be maintained exclusively jointly by the company and Jefferson for 5 years. After that it is open to the public; anybody who wants to can use it.

Senator McCLELLAN. How much is it going to cost you to develop it?

Mr. FORMAN. It won't cost less than $1½ million the way it looks, because from the investment already made, and what is predicted, it will easily run that amount, probably more.

Senator McCLELLAN. How many years is it going to take to perfect it?

Mr. FORMAN. I cannot predict that. Our scientists are unable to tell us yet. We hope within the next year or two, but we cannot say.

Senator McCLELLAN. You don't know how soon you can get the product perfected?

Mr. FORMAN. No, sir; I do not know that, sir.

Senator McCLELLAN. Well, in the meantime, are lives being lost, by reason of that invention not being available?

Mr. FORMAN. Well, it is hard to predict whether lives or how many lives are being lost. But you have to think of it in these terms. Each open heart surgery may use 10 or a dozen pints of blood. It is not easy to get live donors for a particular operation when needed by the surgeon. It would be a great boon if he could have blood on the shelf for several months. The same thing would happen, for example, if we were going to ship blood to Vietnam. It would quite possibly go bad before they could use it on the battlefield.

Senator McCLELLAN. In other words, it is very beneficial, or will be very beneficial, in the health field if this process can be developed to where blood can be preserved for a much longer period of time than it can be now; is that correct?

Mr. FORMAN. Yes, sir.

Senator McCLELLAN. This is a current illustration in this field.

Mr. FORMAN. This is so current, this is happening today. The agreement was completed last December.

Senator McCLELLAN. Now, if I understand you correctly, you did offer this to all companies in that field, all the laboratories.

Mr. FORMAN. Jefferson did. They tried and found only five that said that they could do it, but only one actually volunteered to try.

Senator McCLELLAN. Well, of course, I would regard this as a kind of an extreme case, would you not? This is not just an ordinary situation.

Mr. FORMAN. It is hard to answer that question, Senator. I do not know what you mean by extreme.

Senator McCLELLAN. Well, maybe that is not the proper word. You would not encounter the same problem ordinarily in the processing of a new drug or a new technique in medicine, would you? Or would you? I don't know.

Mr. FORMAN. As long as there is a great risk, and the probability of failure is great, you are going to find fewer and few companies wishing to invest money, time, and personnel in developments of that type.

Senator McCLELLAN. All right. Proceed with your statement.

Mr. FORMAN. With regard to that third point I made, about the position taken by the proponents of S. 1899, this is my answer.

If there is a legitimate danger to our society in concentrating too much wealth and too many opportunities to get wealthier in the hands of a limited number of corporations, the answer may lie in the Government's finding ways and means to give out its contracts to

as many other parties as possible. But once the contractors are selected, preventing companies from obtaining patent rights out of Government contracts may not solve anything. Such a policy may only deprive the Government of worthwhile contractors or may result in contractors devoting their second best personnel to work on Government projects while reserving their best people to work on their own commercial projects so that they could keep title to inventions arising out of them and thereby get some protection for their investment.

Now, I understand from being here previously that the subcommittee would like to have examples of contractors who have refused to take contracts because of this principle. I know how difficult it is to produce examples like this, although we privately hear about them all the time by people representing one company or another.

I did, however, go back into the records of the Mitchell subcommittee, which in August to December 1959 had hearings with regard to proposed amendments to the patent provisions of the Space Act. At that time one of the Congressmen who was sitting on the committee asked specifically for documentation to prove that particular point. The man he asked, who happened to represent the American Patent Law Association, did come back some time later with letters submitted by five companies, and these can be found referred to in the printed report to those hearings for Public Law 85–568, page 412. The five companies were the Electric Storage Battery Co. of Philadelphia, the National Research Corp. of Cambridge, Mass., Corning Glassworks of Corning, N.Y., AMP, Inc., of Harrisburg, and Bowmar Instruments Co. of Fort Wayne, Ind. All five said that because of the title-taking clauses they would not accept NASA contracts—I think most of them had to do with the then new Project Mercury.

If we want to know why it is so difficult to get companies to stand up and be counted as they did, perhaps the reason is that the same Congressman, upon receiving these letters, wrote back to the presidents of those companies and said, "This is your position as it has been represented to us, but surely there must be some mistake—this would make it appear to us as if you are not interested in cooperating with the Government of the United States on this important project."

Each of these companies wrote back and reaffirmed their position in no uncertain terms. But, nevertheless, this news did get around the country like wildfire, and I think because of it, as much as anything else, Senator, many companies that might otherwise come forward have refrained from doing this because they fear such intimidation and possibly reprisals in the form of being blacklisted from working on future contracts with the Government.

Now, gentlemen, it appears to me that this last point is the crux of the entire platform upon which Senator Long stood when he introduced S. 1899. All the other points are merely subsidiary or corollary to his concern over the possibility that retention of patent right by Government contractors will permit them to get a stranglehold on our economy.

As Senator Long said on May 4, 1965, in introducing S. 1899—and here I quote two brief paragraphs from page 9027 of the Congressional Record for that day—he said:

> Mr. President, this is not merely an economic problem. This concerns our liberty and freedom to the extent that, through the granting of monopolies, areas of our economic life are barred to many of our citizens—to that extent is our freedom abridged.
>
> Scientific and technological research conducted or financed by the U.S. Government represents a vast national resource, which could equal or surpass in actual or potential value the public domain open to settlement in the last century. Because the control of patent rights and inventions resulting from such activities means the control of the fruits of this resource, it is the function of the Government to make the results of research available for use by the entire American public which has made this research possible.

I agree 100 percent with this last portion of the statement by Senator Long. It is the function of the Government to make the fruits of any research, which has been subsidized even only partially by Government funds, to the public at large. The real issue is how is this to be done so as to do the most good for the most people.

Should it be done under the time-tested operation of the American patent system, with its inducements for private investment of capital and labor? Should it be done by the Government itself through its own building and operation of plants, followed by market distribution, and so forth? Or should it be done by the Government's free dissemination to everyone of the rights to practice the inventions?

If there is any doubt in Senator Long's ultimate objective, regardless of anything in S. 1899 which may appear to the contrary, this doubt is eliminated by his embracing the philosophy spelled out by his assistant, Mr. Benjamin Gordon, in the article which was reprinted in the Congressional Record following the printing of S. 1899 at pages 9031 to 9033.

In his final paragraph concluding the article, which was devoted to a comparison of "Government Patent Policy and the New Mercantilism," in which Mr. Gordon sees in the policy of leaving title with Government contractors a strong similarity to the mercantilism of the Middle Ages, he says:

> If this comparison elicits the reply that the national interest requires monopoly grants as a necessary stimulation of enterprise, the question arises whether the price we are paying is far too heavy, even if the means could secure the end, for involved is the sacrifice of the citizen's economic freedom.

Now, this philosophy of Mr. Gordon, which Senator Long has apparently endorsed, indicates a belief that the operation of our economy under our patent system is not in the public interest.

Senator BURDICK. Is that an article by Mr. Gordon?

Mr. FORMAN. That is the concluding paragraph of the article by Mr. Gordon; yes, sir.

Senator BURDICK. It appears in the Congressional Record?

Mr. FORMAN. Yes, sir.

Senator BURDICK. What is the date of that?

Mr. FORMAN. May 4.

Now, gentlemen, with 70 percent of all the R. & D. funds now being financed by the Government, such a belief by the proponents of S. 1899 would seem to be an important first step in the elimination of our patent system altogether.

This, gentlemen, I submit is the behind-the-scenes real threat of that bill. It would be the beginning of the end of a system designed to induce people to invest labor and money to make risky inventions worth while.

As the Senate Subcommittee on Patents, I think this threat should be kept in your minds when you review the merit of all the bills under consideration.

It does not matter to me what manner or means are employed to conserve and promote the utilization of our inventive productivity. That productivity is limited. It is one of our greatest national assets. What matters is that every worthwhile invention should be given every possible chance of being developed for use by the people, all the people.

In conclusion, let me point out that I speak not for the patent system, not for the patent profession, not for industry, not for any segment of these. I speak only as a citizen who has for almost 20 years studied and critically observed the developments in the field of Government patent policy, and who is seriously concerned over the possibility that a good deal of our limited inventive productivity will become wasted if not developed under the inducements offered to all the people under the patent system.

This is what will happen under a law like S. 1899 which will tend to take title to most of the inventions made in the United States and put them in the public domain where interest in developing them will lag if not fade into insignificance.

It will not happen under S. 1809 because that bill will tend to leave title with the contractor in a maximum number of situations—that is, I might say, a maximum number consistent with today's political opposition caused by the "patent giveaway" theorists.

S. 1809 tends to assure maximum utilization of the invention by means of compulsory working and/or compulsory licensing requirements. This is good. In exercising those prerogatives, the Government will exercise its true and proper functions. As a contributor to the development of the inventions, the Government is in partnership with the contractor. As a partner, it has certain rights. In this case, it is not to share in cash profits, but in seeing that the other partner puts the inventions to the widest possible use so that the public will benefit thereby. That is the Government's right and obligation. That compulsion is as far as the Government ought to go in promoting utilization of the inventions in most cases.

S. 1809 is not perfect, it needs amendments. I have proposed some in my formal written statement. Others have been suggested by those who have testified before me. Nevertheless, I see in S. 1809 the basis for legislation which comes closest to being the most sensible, workable compromise that has a reasonable chance today of being acceptable to the Congress and also to all who are critical of the general philosophy, as well as the specific provisions of S. 1899.

Gentlemen, S. 1809 is in the true public interest. S. 1899 is not.

Thank you very much for this opportunity today to speak.

Senator McCLELLAN. Thank you, sir.

Senator Burdick?

Senator BURDICK. Of course, Mr. Forman, you understand that you are merely giving your opinion—that if the Government retained title to these patents they would lie fallow. That is just an opinion of yours.

Mr. FORMAN. Yes, sir. Of course, it is always an opinion until we have a chance to demonstrate that it becomes a fact.

Senator BURDICK. You and I know that the Patent Office is full of patents owned by private individuals that are lying fallow. The whole thing is to get together an economic package that is worth while producing.

Mr. FORMAN. That is correct, Senator. And that is why I urge upon you, sir, and upon your colleagues, that you have got the greatest opportunity and, I might say, the greatest obligation under the Constitution, to do something about it. With all these inventions coming out of Government research, as long as you have got this policy written in S. 1809, whereby the Government will keep a watchful eye under compulsory working or licensing requirements, and make sure that the inventions are put to use by the contractor who retains title—you have done all you should want to do in order to get them into use.

Senator BURDICK. You have no assurance that because title is in the name of a private person the invention is going to be put to work.

Mr. FORMAN. You are absolutely right. But you will have that assurance if you let the contractor keep title subject to the restriction that, if he does not put them into commercial use, he will lose the right to keep title. The chances are that the contractor in many cases will work the invention if he knows that the Government will take them and give them to somebody else, or compel him to grant licenses to another party.

Senator BURDICK. What period do you recommend for that?

Mr. FORMAN. I have recommended a 5-year period.

Senator BURDICK. This is something new.

Mr. FORMAN. Well, it is not exactly new. It has been written about, it has been proposed. This has actually been going on in many countries around the world. Compulsory working and compulsory licensing are not new. They would be new to the United States.

Senator BURDICK. In other words, your suggestion will be that, in these Government contracts, where the equities will justify it, to permit the individual contractor to have title, but if he did not exploit it in 5 years, it would revert to the public.

Mr. FORMAN. That is right. It would either revert directly back; that is, it would be placed in the public domain, or maybe some arrangement might be made whereby the Government would say, "Let's find somebody else who is interested in working it." That is all I am pleading for. Get the invention into public use.

Senator BURDICK. One of the things that bothers me, when you gave this example about this blood rejuvenator, whatever it was, that even though that private patent might have been issued in the name of a private company, there is no particular assurance that the $2 million would be spent by them, either.

Mr. FORMAN. Senator, let's take that one step further. Consider what happens to any patented invention made by private invest-

ment—where there is no Government investment and no Government rights at all. Under our patent laws, there is, of course, no assurance that the invention will be worked. You are absolutely right. However, this is in accordance with the contract, the bargain that the Government has made with the patentee, in return for his having publicly disclosed the invention—instead of trying to keep it as a trade secret, as they did in the medieval period. He is being told, "You can have the right to exclude others from manufacturing this invention. We will limit you, however, to a period of 17 years. You have got to make of it whatever you can and wish in that period. At the end of 17 years it is in the public domain"—which has always seemed like a fair deal.

Now, that is in the private sector.

We have no way of giving any further compulsion to make the inventor or patent owner—who puts out his own money, his own time and services and so forth—to make him use the invention. That is true. There is no special compulsion other than the fact that each day he fails to work the invention while possessing the right to exclude infringers brings him closer to the end of the patented term when anyone thereafter will be able to compete with him without fear of being stopped by a lawsuit.

But you have an additional lever here. You have got this right. I say the Government is a partner in this invention. It has made a contribution to the invention. The equity is there.

I have long ago recognized this.

But I say it is wrong for the Government to take title, and then do nothing with it. You have got a choice to make. It is a basic decision which must be made, a basic philosophy which must be established at this point.

Is the Government going to adopt a policy where we take title to so many inventions? If we are not going to do something with them, this is wrong.

Senator BURDICK. Just a moment. That is an assumption that nothing is going to happen to inventions whose title is acquired by the Government.

Mr. FORMAN. We have to operate on this assumption. The point is, if you enact legislation so that the Government ends up with a massive collection of inventions, it has a basic choice to make: Either it works them or it doesn't. If it doesn't work them, it is possible that nobody will. If it does work them, this will be a fundamental change in the philosophy of our society. Do we want the Government to get into business on a mass scale? If we do, let's take title to all the inventions and put the Government in business.

If the Senate and the House decide this is best for the country, then let them go ahead and write it into law, but they should at least recognize and clearly state that this is what they intend to do.

Senator BURDICK. No one wants the Government in business. They are taking these patents for the people.

Mr. FORMAN. That is a fallacy, sir. I believe the whole theory of Senator Long is wrong. He says this will not happen. But this is precisely what will happen. If the Government does not exploit it, as S. 1899 says it will, the only other choice is to leave it open to the

public. And I can only predict complete failure. You say this is an opinion. Of course it is. But can we take the chance? Can we take the chance that thousands of inventions every year will go unused? If we do, the Government will only be adding to the very problems which you pointed to yourself.

Senator BURDICK. You acknowledge that thousands of private inventions are going unused.

Mr. FORMAN. I don't question the point. If this is wrong—maybe the solution is, as has been suggested, shorten the 17-year period. We cannot discuss this now. But if the Congress thinks it is too long a wait, it could shorten it. But the point is that just because that is bad or wrong, do you want to aid and abet it by adding thousands more patents under Government contract situations, and put them in the public domain, where nobody is going to use them? If we do, our technology will end up so far behind Russia's we will never be able to catch up with them.

Senator BURDICK. I don't agree with your concluusion. But I will say that the 5-year limitation has added something intriguing to the record.

Mr. FORMAN. Well, sir, I hope you will find it acceptable as a substitute for the title-taking philosophy of S. 1899. And this hope applies, of course, to your colleagues who have thought the proposal by Senator Long, whom I admire—I said so in my statement—I think he has done a great service because he has brought this tremendously important matter to the attention of all—even though I think his solution is dead wrong. But at least he recognizes the problem. He and I agree on a fundamental point, namely that our main objective should be to get the inventions into the public hands. But we should not just do this by opening them up to everybody. Almost everyone who has testified here has told over and over how this will kill the inducement to convert most inventions into commercially useful embodiments.

Now, if you cannot accept it, if the examples you heard are not sufficient, then write something like what I have advocated into the law—and I think S. 1809 already has it. If it has not, it is in S. 789. Write in a provision whereby the Government can do something affirmative about these inventions—instead of just leaving them to anybody, instead of going into business and manufacture—let the contractor keep them. But, if he does not do something with them for the public good, let the Government take them back and find somebody else who is willing to develop them. Or if that does not work, then put the inventions in the public domain.

Senator MCCLELLAN. Thank you very much, sir.

The subcommittee has held 5 days of hearings on this subject, and the bills that are pending. We have heard 26 witnesses. A number of statements have been submitted for inclusion in the record. Although I want to expedite the subcommittee's action on this subject, I also wish to receive the counsel of all those who have a contribution to make.

Therefore, additional hearings may be held. Incidentally, the Chair today is sending out a letter to each Senator asking if he has any witnesses that he thinks could contribute anything to this. I do not want these hearings to close denying anybody whatsoever from having the opportunity to fully present their viewpoints.

The hearings will be recessed subject to call. That does not mean that this is going to be prolonged indefinitely. I am trying to expedite them to a conclusion, but without setting anybody off who really believes he has a contribution to make.

The committee will stand in recess.

(Whereupon, at 11:35 o'clock a.m., the subcommittee was adjourned, to reconvene subject to the call of the Chair.)

GOVERNMENT PATENT POLICY

TUESDAY, AUGUST 17, 1965

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
TRADEMARKS, AND COPYRIGHTS OF THE
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 3302, New Senate Office Building, Senator John L. McClellan (chairman of the subcommittee) presiding.

Present: Senators McClellan (presiding), Burdick, Scott, and Fong.

Also present: Thomas C. Brennan, chief counsel; Edd N. Williams, Jr., assistant counsel; and Stephen Haaser, chief clerk, Subcommittee on Patents, Trademarks, and Copyrights; Horace L. Flurry, representing Senator Hart.

Senator MCCLELLAN. The committee will come to order.

The subcommittee this morning resumes public hearings on the pending bills relating to various aspects of Government patent policy. Since the last session of the committee on July 7, the minority leader, Senator Dirksen, introduced a bill on this subject, which is S. 2326. This bill has been referred to the subcommittee and will be included as a part of these hearings.

(The bill, S. 2326, referred to appears on p. 30 of part 1.)

Senator MCCLELLAN. I don't know whether there is anyone here to testify specifically on that bill, but if so we will hear them. In the final markup of a bill, and during the subcommittee's deliberations, with respect to all or any of the proposals his bill will be considered.

At the conclusion of the last hearing held on July 7, I wrote a letter to all members of the Senate inviting their suggestions as to any additional witnesses whose testimony they thought should be heard by the subcommittee before the hearings on these bills were concluded. I state very frankly the purpose in doing that was to make certain that no Senator, and no one else so far as I know, would be able to say that the committee declined or refused to hear anyone who had any contribution they thought they could make to these hearings or to a resolution of the issues involved.

I now direct that a copy of this letter be printed at this point in the record together with the written replies which I received from 13 Senators. I may note that only three Senators requested witnesses to be heard, and the subcommittee has sought to make possible the appearance of those whose testimony was requested. In one instance, I believe it was Senator Kennedy of New York who suggested in his reply that

he had looked over the list of witnesses and that he saw that no representative of the Department of Justice had testified, and he requested that Assistant Attorney General Donald Turner of the Antitrust Division be invited. He knew that Mr. Turner had done some work in this field, and thought it might be well to invite him to testify. Now I may say that the Department of Justice has been invited to testify. On two occasions heretofore they have suggested that they preferred simply to send down a statement. They didn't care to appear and testify personally.

Has that statement been received?

Mr. BRENNAN. Yes, Senator, it has.

Senator MCCLELLAN. The statement has been received and, of course, it is a part of the record.

After we received this letter from Senator Kennedy we again contacted the Department and they said all they cared to do was submit a statement.

All of the letters we received will be placed in the record and printed at this point.

(The letters referred to follow:)

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS,
July 7, 1965.

Senator ——— ———,
U.S. Senate,
Washington, D.C.

DEAR SENATOR: The Subcommittee on Patents, Trademarks, and Copyrights has just concluded 5 days of public hearings on four bills relating to various aspects of Government patent policy. Three of these bills (S. 789, S. 1809, and S. 1899) are principally concerned with the ownership of patent rights in inventions arising under Government-financed research and development contracts or grants.

The subcommittee has heard testimony from 26 witnesses, including Members of Congress, executive departments and agencies, and representatives of industry, the bar, and scientific groups. A number of additional statements have been filed for the record. The subcommittee also held hearings on this subject during previous Congresses, and a number of staff studies, describing the patent practices of the various agencies, have been published.

Notice of the subcommittee hearings appeared in the Congressional Record, and the subcommittee has heard every witness who requested the opportunity to testify. I believe that the subcommittee has developed a thorough record. However, in view of the great interest which many Members of the Senate have indicated in this issue, I would welcome any suggestions which you may have concerning additional witnesses whom you think the subcommittee should hear before these hearings are closed.

I am attaching a list of the witnesses who have appeared during the recent hearings.

Sincerely,

JOHN L. MCCLELLAN, *Chairman.*

U.S. SENATE,
Washington, D.C., July 12, 1965.

HON. JOHN L. MCCLELLAN,
U.S. Senate,
Washington, D.C.

DEAR JOHN: This is to acknowledge receipt of your letter of July 7 in which you inquire as to whether or not I know of any additional witnesses that the Subcommittee on Patents, Trademarks, and Copyrights would heard regarding Government-financed research.

Although the hearings have prompted considerable amounts of interest in the State I have heard of no special requests to appear before the committee.

I am taking the liberty to send your letter to my former assistant, L. Ralph Mecham, who is currently assistant to the president of the University of Utah. If he has any suggestions for witnesses I will be glad to forward them to you.

Sincerely,

WALLACE F. BENNETT.

U.S. SENATE,
July 14, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Senate Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your recent letter and the enclosure concerning the hearings on bills relating to various aspects of Government patent policy.

My own State of Colorado does have a large number of firms holding Government research contracts. I am now attempting to contact some of these firms and their representatives in order to see if they wish to submit statements. If they do so wish, I will inform you at the earliest possible time.

Best regards.

Sincerely,

PETER H. DOMINICK,
U.S. Senator.

U.S. SENATE,
July 14, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: With reference to your letter of July 7 with respect to any suggestions concerning additional witnesses to be heard by the subcommittee on S. 789, S. 1809, and S. 1899, I know of no other witnesses who desire to be heard.

Several of the Government agencies have testified. It is assumed that Senator Eastland has or will request statements from all of the Government agencies which engage in research and development contracts with respect to patent policy being followed by such agencies and their views with respect to the bills pending before the subcommittee.

Sincerely,

PHILIP A. HART, *Chairman.*

U.S. SENATE,
July 15, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Patents, Trademarks, and Copyrights Subcommittee, U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter concerning the hearings on Government patent policy.

These hearings, with the impressive list of witnesses, will be most helpful on this troublesome question. I will follow this matter with interest.

At this time, I do not have any witnesses to add to the list.

Best regards.

Sincerely,

ROMAN L. HRUSKA,
U.S. Senator, Nebraska.

U.S. SENATE,
July 12, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter requesting any suggestions as to additional witnesses who might be heard by the Subcommittee on Patents, Trademarks, and Copyrights on the various Government patent bills.

At present I do not have any additional names to submit.

Sincerely,

DANIEL K. INOUYE,
U.S. Senator.

U.S. SENATE,
Washington, D.C., August 2, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: I hope I am not too late in answering your letter of July 2 asking for suggestions concerning additional witnesses whom the subcommittee might hear on the question of Government patent policy.

In looking over the list which you sent, I saw no representative of the Department of Justice. I know that Assistant Attorney General Donald Turner of the Antitrust Division has done a good deal of thinking on this subject, and if he has not already been invited, I suggest that he would be a very helpful witness.

Again, I apologize for my tardiness in responding to your letter.

Sincerely,

BOB F. KENNEDY.

U.S. SENATE,
June 28, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR JOHN: I have followed with considerable interest the hearings held by your subcommittee pertaining to the various patent bills S. 789, S. 1809, and S. 1899. S. 1809, which you have authored makes a very important contribution to the possible solution of the complex problem involving inventions developed under Government contracts because it recognizes the fact that equities of all parties to an invention must be considered in determining patent rights. Hence, a solution which would require the Government, always, or never, taking rights in inventions is not the proper one. I therefore agree with and support your proposal.

I would suggest, however, one possible change for your consideration. Since Government contractors include a number of educational institutions and nonprofit research organizations, I believe you might consider including these groups in your bill. While such educational and nonprofit organizations do not have "commercial" positions in that they are not manufacturers or producers of products, they do enjoy commercial status insofar as licensing inventions is concerned. They also rely on such revenues as a source of additional research funds within the particular university or research community. Thus, their reasons for enjoying whatever benefits may be available under your bill are as strong and valid as those relating to manufacturing concerns.

The University of California, I understand, has proposed the attached amendment to S. 1809 which would include educational institutions having definite, established patent policies requiring assignment of inventions. I hope you will find this request a reasonable one and urge that your subcommitee might adopt language along this line.

Sincerely yours,

THOMAS H. KUCHEL.

UNIVERSITY OF CALIFORNIA—PROPOSED AMENDMENT TO S. 1809 TO INCLUDE EDUCATIONAL INSTITUTIONS

Section 4b, page 8, beginning line 5:

"tablished nongovernmental commercial position *or, in the case of an educational or nonprofit institution contractor which has a definite, established policy, approved and promulgated by its governing body, of retaining or acquiring, title to inventions made by its employees or of requiring its employees to assign title to such inventions to a patent-holding entity for the benefit of the institution,* the agency head shall acquire no greater rights than the nonexclusive."

U.S. SENATE,
July 16, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Have received your recent letter concerning the hearings of the Subcommittee on Patents, Trademarks, and Copyrights on certain patent bills and the enclosed witness list. Appreciate your thoughtfulness in writing with respect to this matter. Do not have any suggestions as to additional witnesses.

Can assure you I look forward to the recommendations of your subcommittee.

Kindest regards.

Sincerely,

EDWARD V. LONG,
U.S. Senator.

U.S. SENATE,
Washington, D.C., July 15, 1965.

Hon. JOHN L. MCCLELLAN,
U.S. Senate, Washington, D.C.

DEAR SENATOR: Thank you for your letter of July 7 concerning the public hearings before your subcommittee on several bills relating to Government patent policy and asking my suggestions for any additional witnesses who might appear before your committee.

The witnesses who have already testified before your committee appear to me to cover the spectrum and I do not have any names to offer. I do want, however, to commend you for holding these hearings and I am confident that your committee will develop some strong recommendations for the formulation of a fair Government patent policy.

With best wishes and kindest personal regards, I am,

Sincerely yours,

MIKE MONRONEY.

U.S. SENATE,
July 21, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your letter of July 7, requesting suggestions as to possible further testimony at your patent hearings.

My interest in patent matters had led me to introduce bills on NASA patent policy in the 88th and 89th Congresses and to participate in the continuing consideration of the issues before the Senate Select Committee on Small Business.

Although I am aware of the chairman's desire to conclude the hearings as soon as possible, I would like to request an appearance in order to present a statement of my views on this important subject. If this request is granted, I am prepared to testify at any time that would be convenient for the subcommittee.

Sincerely,

WAYNE MORSE.

U.S. SENATE,
July 12, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Committee on the Judiciary, U.S. Senate,
Washington, D.C.

DEAR SENATOR MCCLELLAN: Permit me to acknowledge and thank you for your letter with reference to the hearings which have been concluded on several bills relating to Government patent policy.

I am very glad indeed to have the benefit of this information; however, I am not aware of any additional witnesses that should be called.

With best wishes, I am,

Sincerely,

RICHARD RUSSELL.

U.S. SENATE,
August 6, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Old Senate Office Building,
Washington, D.C.

DEAR JOHN: I am deeply concerned that the record of the subcommittee's hearings may not be as complete as it could be as to what effect unwise Government patent policies might have on future scientific research undertaken in our institutions of higher education.

It occurs to me that some of the bills on which we are holding hearings might be construed in such a way as to vest in the Government title to all inventions and discoveries from research in our colleges and universities which have received Federal grants for any one of a number of purposes, even including financial aid for the construction of scientific facilities.

I believe that you share my concern. For this reason, I would like to suggest that an invitation to appear before the subcommittee at its hearing of August 17 be extended to J. William Hinkley III, president and director of Research Corp., 405 Lexington Avenue, New York, N.Y.

Mr. Hinkley's organization handles the patent policy matters of a substantial number of the Nation's outstanding colleges and universities, and as such, is qualified to discuss with the subcommittee the patent policies of such institutions as well as the effect the pending bills would have on the future of scientific research in them.

Kindest regards.

Sincerely,

HUGH SCOTT, *U.S. Senator.*

U.S. SENATE,
July 13, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Senate Office Building,
Washington, D.C.

DEAR JOHN: Thank you for your courtesy in informing me of the status of your hearings on the present patent legislation.

I, of course, share with you the belief that these are most important measures, and I appreciated the opportunity to appear before your subcommittee and to testify in person.

Let me take this opportunity to thank you for the courtesy shown me by you and the members of your subcommittee at that time, and to assure you that I believe that you have given full and fair consideration to all these measures.

With warmest personal regards,

Sincerely,

HARRISON A. WILLIAMS, JR.

Senator McCLELLAN. With the approval of my colleagues on the committee, the Chair would like, in order to expedite these hearings but not to deny anyone the right to be heard, we are going to invite each witness, if he will, to try to confine his statement to 15 minutes. I want to say that we hope you will try to give your statement succinctly and concisely and be brief so that we can accommodate all of those we have scheduled.

Senator Fong, do you have any statement?

Senator FONG. No, thank you, Mr. Chairman.

Senator McCLELLAN. Thank you very much.

The first witness is Dr. James A. Shannon, Director of the National Institutes of Health.

Dr. Shannon, we are glad to welcome you this morning. You have someone with you?

Dr. SHANNON. Yes, sir; I have Mr. Richard Seggel, who is my executive officer at the National Institutes of Health, for any technical backup.

Senator McCLELLAN. All right, Doctor.

I note you have a prepared statement. Do you wish to read it or do you wish to place it in the record and highlight it?

Dr. SHANNON. I would rather read it, sir.

Senator McCLELLAN. You may proceed.

STATEMENT OF DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH; ACCOMPANIED BY RICHARD L. SEGGEL, EXECUTIVE OFFICER

Dr. SHANNON. Senator McClellan, and members of the committee, I appreciate the opportunity afforded by your invitation to appear before this committee and discuss the relationships of patent policies to NIH programs, especially as it concerns research financed by multiple sources or situations where additional private funds are necessary for the full development of an invention. At the outset, I would emphasize that the NIH as one of the Bureaus of the Public Health Service, is a component of the Department of Health, Education, and Welfare, and functions within the patent regulations set forth by the Department.

I understand that the Department's patent policies and its position on the legislation before this committee have already been presented. For this reason, I will limit my statements to the two areas of concern mentioned in your invitation.

I would first like to address myself to situations where additional private funds are necessary for the full development of an invention made under Federal support, since I believe the policy problems attending these situations are a major public concern.

Senator McClellan, I would like to say parenthetically that while I talk about drugs in this particular statement, this also would include biologics and the whole range of related materials, but for simplicity I will limit my specific comments to therapeutic agents.

The NIH supports research activities through grants, contracts, and within its own laboratories which may result in the discovery of potential therapeutic agents. Before one of these agents can reach the marketplace for public consumption, it must travel a long road, usually measured in years, from discovery to complete development. This road includes the actual discovery of the potential therapeutic agent, the preliminary screening to determine if the agent has possible therapeutic utility, different stages of animal testing, preliminary tests in humans, and, finally, full-scale clinical testing of the agent. The newly discovered agent may be a completely new chemical entity or an old chemical either of which is shown to be useful as a therapeutic. The developmental process in either case is governed by the Federal food and drug laws which require evidence of careful testing before the agent can be cleared for the market.

In most instances the NIH or its grantees do not participate in the full development of a therapeutic agent up to the point where it is made available commercially. We view our role in the Nation's medical research effort as complementary to the activities of the other elements within our society, both public and private, that also support research and development related to health. It seems to us that the interests of the American people are best served when the various elements of this medical research structure can interact. The most effective interrelationship results when the particular capabilities of the various elements, Federal and non-Federal, can be utilized to the fullest extent.

Generally speaking, the NIH scientist or grantee will be involved, if at all, at one of four points in the development process:

(*a*). NIH funds may be involved in the organic synthesis of a compound and perhaps in a portion of its screening in a biological system. We may participate in animal and clinical testing but will not usually, except in psychopharmacology and cancer chemotherapy, pursue this to a definitive conclusion.

More generally the chemist, given freedom of action, would approach the pharmaceutical industry which has extensive capability to undertake the entire development and testing process and is able to accumulate all the data from different stages of development necessary for FDA acceptance.

(*b*). NIH funds may also be involved in support of research which involves the probing of biological mechanisms with chemical agents. Out of such investigation may well come new knowledge on novel uses for a compound, but in general such an investigator will rarely have the capability of followthrough as is the case with a wholly new therapeutic agent.

(*c*) NIH funds more recently support broad clinical investigation and such work has a heavy commitment to the assessment of therapeutic activity, either in absolute or comparative terms, of a number of chemical substances. Out of this type of work in the past has come wholly new therapeutic uses that have had broad impact on clinical medicine.

Without regard to NIH programs, I have in mind in this respect the discovery of the tranquilizing properties of reserpine when this drug was in use as a blood pressure lowering agent and the dicovery of energizing properties of isoniazide when the drug was being explored as an antitubercular agent.

(d) Finally, NIH has, in the past, supported and/or participated in the extensive type of field trial which firmly establishes the net benefit to be derived from a given compound under well-defined clinical conditions, and will no doubt do so in the future.

The first three of these types of studies can be expected to yield patentable discoveries and consequently the rate of evolution to an effective therapeutic agent generally available to the public will be determined by the terms and conditions which facilitate the interplay of the resources of the Federal Government, the university scientists, and the pharmaceutical industry.

Although NIH support of an investigator may stop at an early stage of development or cover only a part of the complicated sequence of drug development, our departmental patent policy requires that his invention be reported to the Surgeon General for his disposition, that is, the Surgeon General's disposition, since the invention in most instances is complete within the definition of the U.S. Patent Office. The Surgeon General's disposition generally results in title to the Government in accordance with the provisions of the Department's regulations, the title provisions of the President's memorandum and the Executive order governing disposition of employee inventions.

The uncertainties involved in after-the-fact determinations have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application. The industrial firms want some guarantee of exclusive patent rights as compensation for and protection of their possible investment, which may be considerable before FDA clearance can be obtained. Because, as I understand it, there is some question as to whether we can or should extend such a guarantee, it is often difficult to motivate industry to undertake the perfection and marketing of the NIH-supported inventions, and by an NIH-supported invention I have in mind those which were made under circumstances wherein a part or all of the support was derived from the National Institutes of Health.

We, of course, support the basic policy that title to health and welfare inventions generated primarily with Federal support should reside in the Government. It does seem to us as persons responsible for the largest Federal medical research program that there does need to be clarification of the situation with regard to the issuance of licenses to inventions held by the Government. One possible solution might be the granting of short periods of exclusivity in such situations as I have discussed—that is, where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industrial cooperation. Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug is cleared by the FDA and indeed marketed. We also believe that is seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes.

The Department is in the process of reviewing its entire patent policy and practices that relate to this matter.

Passing on now to the second area on which you wished my comments, I would note that one of the common characteristics of scientific research activities performed in universities is receipt of joint and simultaneous support from Government and nonprofit organizations, and not infrequently from industry. In the biomedical sciences, the Government support is most frequently provided in the form of a grant from the NIH. Funds from these different sources of support are often commingled with the result that a given research project may be financed and dependent upon several different sources of income at the same time. Where the private sources of support impose no conditions upon their grant relating to inventions, the HEW regulations requirement that the NIH grantees report all their inventions to the Surgeon General for his disposition poses no technical problem. However, where, as in the case of the American Cancer Society and the American Heart Association, cosponsors maintain patent policies requiring their grantees to agree to assign all invention rights to them, the grantee who accepts support for the same research activity from both the NIH and such other sponsors has undertaken conflicting obligations he cannot fulfill. It is difficult to solve problems of conflict after the fact on the basis of priority as between the cosponsors. Neither is it a satisfactory solution to suggest that the grantee be limited to acceptance of support from only a single source which imposes such an obligaiton.

I believe it is in the public interest to encourage support of research from the private sector of our economy and to discourage exclusive reliance upon Government-financed support. In order to further this objective, it may be necessary to relieve universities and their research workers from the dilemma created by conflicting obligations to assign patent rights.

At the present time, it is my understanding that the patent regulations of our Departmen do not take into consideration the equities of cosponsors in making disposition of inventions arising from research financed by multiple sources, and the Surgeon General must make his determination solely on the basis of our support. As I have mentioned, I do understand that these regulations have been under review for some time with this matter being given consideration by the Department.

Thank you very much for this opportunity to appear before you. I would like to emphasize that I am obviously not a patent expert, but I would be glad to answer any questions from my perspective as the director of a large Federal research activity.

Senator McCLELLAN. I haven't had an opportunity to read your statement. I have tried to follow you, so I may not be able to interrogate you about it closely. But I note you say on page 2:

> In most instances the NIH or its grantees do not participate in the full development of therapeutic agents up to the point where it is made available commercially.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Why don't you? You participate in it up to the point where it becomes evident that it is patentable; is that right?

Dr. SHANNON. Yes, sir.

Well, a patent may issue on information developed quite early in the total development.

Senator McCLELLAN. Yes, but you do not participate in the final testing and processing, developing, and getting it ready for marketing.

Dr. SHANNON. This is correct, sir, except in the special instances of psychopharmacology and cancer chemotherapy where we feel that we have an additional responsibility.

Senator McCLELLAN. Let me ask you this: At the point where your assistance ceases, suppose nothing is ever done beyond that in some of these instances, maybe not in all, but in those that you are referring to here. If nothing is done beyond that, would the public ever get any benefit from it?

Dr. SHANNON. No, sir.

Senator McCLELLAN. Then whose responsibility is it? I will ask you first, is there an investment involved, an expenditure and a risk involved in the further processing of it to bring it to a marketable testing and approved stage to where it is marketable and beneficial to the public?

Dr. SHANNON. Senator McClellan, the answer to both those questions is "Yes." There is an additional expenditure, and there is indeed a very broad risk involved.

Senator McCLELLAN. I have no interest on earth in this issue, except to find out what is best for the public, and also to preserve those principles of patent rights to those who make a discovery, and to give them an opportunity for development.

Now, what is going to happen if the Government goes to the point where it is patentable, but it is not going any farther with its aid and assistance, and that the Government is going to take the patent? Who then is going to process it on their own if the Government is going to keep all rights to it? Who is going to make that investment and who is going to take the risk?

Dr. SHANNON. Senator McClellan, unless terms and conditions are such that it will permit industry to accept the risk within the context of anticipated profit, it is not likely to bring these advances to the public.

Senator McCLELLAN. I am talking about those cases where it is not known, though you have made the discovery, and that is the point when that discovery is made, let's say Government takes title to it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Because it contributed to making the discovery. It helped to finance the research that brought about the discovery. You make the discovery. It is patentable. The Government takes the patent rights, and it stops there. Yet there has to be an investment made. There has to be further testing. There has to be revision. There has to be experimentation. It may take a good deal of money. It may take investment. Certainly it takes talent. It takes trained people. It takes equipment to do it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, if the Government owns the patent, who in private industry is going to make the investment and take the

risk, if its competitor can immediately step in and enjoy or share all of the benefits without making any contribution?

Dr. SHANNON. Senator McClellan, I think very few people.

Senator MCCLELLAN. Well, what is the best, what policy is in the best interest of the American people and of the public generally with respect to it? That is what we are trying to find out.

Dr. SHANNON. Well, my opinion would be that limited exclusively in terms of a license to a commercial enterprise with march-in rights in order to monitor the price and distribution structure would indeed permit negotiations between the Government agency on the one hand and the industrial firm on the other, to undertake the development work that could lead to rapid and effective marketing of an essential discovery.

Senator MCCLELLAN. I can appreciate that abuse might occur and might very well occur if there wasn't some control beyond if you say, well, we will just assign all patent rights to you if you are going to develop it. Now, I don't go along with that.

Dr. SHANNON. No, sir.

Senator MCCLELLAN. I think that may be going too far. There should be, if the Government owns the patent, some way that the Government can offer some incentive to somebody to go out there and take this risk and spend that money to further develop it and process it to the point where it becomes marketable and beneficial to the public.

Dr. SHANNON. I agree completely.

Senator MCCLELLAN. There must be some incentive for that.

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. Unless the Government is going to take over the whole thing.

Dr. SHANNON. Which it cannot.

Senator MCCLELLAN. And you are not equipped to do that.

Dr. SHANNON. No, sir.

Senator MCCLELLAN. You are not equipped to do it. Then there ought to be another restraint when the Government has permitted or when we have permitted that development, we should not permit that interest to exploit it to the extent of profiteering off of it, so to speak, at the expense of the public, and that it should be made available on some basis for some competition.

Now, there may be given an exclusive right for a period of time to develop it and get it marketed and so forth. But then there ought to be some way, some provision, it seems to me, of licensing the use of it, licensing the practice under that patent to others who might be competitors.

Dr. SHANNON. I agree, sir.

Senator MCCLELLAN. Now, how to define, how to develop a statute of such regulations and such procedures as will protect the Government and as will insure those who take the risk and make the investment in processing and developing it to a marketable state, how to insure them some protection that immediately after they have done that their competitor just can't walk in and reap all the benefits of their investment and their risk, it is a very difficult area, and that is the area in which I am concerned about how to find an equitable solution.

Dr. SHANNON. Well, Senator McClellan, I am a technician rather than a patent lawyer, but, if I can define my position this way, there is a very substantial risk in the development of a new drug.

Senator MCCLELLAN. By that you mean the fellow who takes that risk from the time of patent on to development may spend his money and come out and find out it is no good?

Dr. SHANNON. We can put a dollar figure on it, sir. It costs between $200,000 and $400,000 from the initial discovery of an activity to the point where knowledge has been brought to a degree of acceptability by the Food and Drug Administration.

Senator MCCLELLAN. $200,000?

Dr. SHANNON. $200,000 to $400,000.

Senator MCCLELLAN. $200,000 to $400,000?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. That has been your experience?

Dr. SHANNON. This is our crude calculation; yes, sir?

Senator MCCLELLAN. Sir?

Dr. SHANNON. Yes, sir, this is our crude calculation.

Senator MCCLELLAN. Well, now, is there the likelihood that chemical companies and drug companies and so forth would just pick up a patent and go spend that much money on it, take that risk, if when they perfected it, so to speak, and got it marketable, that their competitor could just step in and compete with them?

Dr. SHANNON. Senator McClellan, were I in industry I would not take that risk.

Senator MCCLELLAN. Let me ask you this then. From your experience or observation, what percent of them turn out to be useful and develop into a marketable product of benefit?

Dr. SHANNON. I can't give you a percentage, Senator McClellan, but I would say I can give you an order of magnitude from the standpoint of the initial discovery of activity to a marketable product. It is substantially less than 1 out of 10.

Senator MCCLELLAN. One out of 10?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. In other words, 1 out of 10 becomes useful and beneficial and profitable from a commercial marketing standpoint?

Dr. SHANNON. I would say substantially less than 1 out of 10.

Senator MCCLELLAN. Less than 1 out of 10?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. What happens to the other nine?

Dr. SHANNON. Well, the others drop along the way, and my figure of the $200,000 to $400,000 is the price tag that would provide for full development of the one that was successful. It does not cover the costs of those that are dropped along the way.

Senator MCCLELLAN. I understand, but they are dropped because upon further examination the industry says, well, it is not worth the risk.

Dr. SHANNON. They have less activity than other agents that are already available or they have more toxicity and they do not warrant full development.

Senator McCLELLAN. That is what the inventor or the industry conceives after further examination that they are not worth the risk?

Dr. SHANNON. This is with the development——

Senator McCLELLAN. But on those where they take the risk, where they actually undertake the development, how many of them fail?

Dr. SHANNON. Senator McClellan, that is very difficult to say, because it depends upon the point in the developmental process that you take off from.

Senator McCLELLAN. Do some of them fail?

Dr. SHANNON. Oh, yes.

Senator McCLELLAN. Where they do take the $200,000 to $400,000 investment, some of them fail?

Dr. SHANNON. A substantial number; yes, sir.

Senator McCLELLAN. A substantial number of them fail. So then we come to this point. Where the Government makes an investment in joint operation with private contributors, with a university, and the patent discovery is made which is patentable. Then from there on even where they undertake to develop it into a marketable beneficial product, a substantial number of them fail.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. One out of 10 or less than 1 out of 10.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. So there is a continuing risk involved.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, would you recommend that the Government take that risk?

Dr. SHANNON. No, sir.

Senator McCLELLAN. And that the Government undertake to do it?

Dr. SHANNON. Well, to be very frank, sir, were the Government to do it, it would have to develop in a very substantial fashion precisely the same type of developmental plant that is already is existence in industry.

Senator McCLELLAN. Would not the Government have to go out and contract with some plant?

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. With some private industry to try to develop it?

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. I am just trying to find the equity in the thing and how to approach this thing to get equity out of it.

Dr. SHANNON. Could I draw a parallel, Senator McClellan?

Senator McCLELLAN. Yes. We have taken longer than 15 minutes. I am the one violating the rule here, myself.

Dr. SHANNON. At the present time in research and development, the pharmaceutical industry expends roughly in the order of magnitude of $300–$400 million a year. It is estimated that our total expenditure for medical research in this Nation is about $1.9 billion as of today, as a rate. And the $300–$400 million is 1964 figures.

Current figures would be approximately $400–$500 million. So, roughly, industry contributes approximately 25 percent of all research and development to the biomedical field.

Now, in the development of weaponry, where the sole customer, if you will, is the Government, or in the space program where the

Government is the sole customer, you do not have developed a vigorous private industry that can thrive in the absence of Federal help. In other words, in our DOD activities and NASA we pay the total cost of all developments.

Now, this has never been the case in the chemical industry or the pharmaceutical industry, and in a society that is based upon the profit motive traditionally, it has been possible to develop a very vigorous enterprise within the private sector that has shown great capability of producing good things in the health field.

Now, I do not hold that with the Federal entrance into biomedical research such as has taken place in the last 20 years in a very large way, that all advances that are made through the use of Federal funds should be turned over to this industrial enterprise simply because it has the capability of developing them.

On the other hand, I do believe that terms and conditions for the covering or the protection of patentable entities should be such as to permit normal interplay between those forces of science that exist within the Government and those which exist within the university and those which exist within industry, because in the final analysis, our purpose here is to use all elements of society in the most rapid conquest of disease that is possible.

So that the terms and conditions that relate the expenditure of Federal dollars in relation to an industrial operation such as this should always have this as one of it major objectives. How can we most rapidly develop a compound into a marketable drug, and yet at the same time protect the Government's equity in this? And the Government's equity here is primarily the making available of the medicinal in the broadest possible way, in the shortest possible time, and at the lowest possible price. This is the primary Government equity here, in that we stand to protect the purchaser of the drug.

Senator McCLELLAN. But, Doctor, here is one of the objectives. The Government makes the investment. It helps to develop the process that becomes patentable.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. And it is patented. The Government, that is taxpayers' money that goes into it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, you have discovered the thing, but yet there is private investment in it, too.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Well, now, if the private investor is permitted to take the discovery and exploit it into an enormous profit, even though the public ultimately gets the benefit of the healing qualities or the medical qualities of the drug, is not that particular investor, that particular contributor to the research and so forth that helped develop it from the private enterprise sector, is he not greatly benefited out of taxpayers' funds by reason of the fact that the taxpayers contributed to the original development?

Dr. SHANNON. Yes, sir. I did not suggest that this discovery be given to a private firm for the full uncontrolled exploitation.

Senator McCLELLAN. But you would recommend such an arrangement as a license or something that would present to him a proper incentive?

Dr. SHANNON. Yes, sir; this I would.

Senator MCCLELLAN. To make the investment?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. To further development and to get it on the market?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. I am trying to find a middle ground somewhere that is right between everybody.

One other question and I am through, the question of whether you are permitted to testify freely. Are you down here carrying out some administration's theme or department's theme or are you down here talking to us from your own knowledge and exercising your own free judgment, and so forth?

Dr. SHANNON. Senator McClellan, when I cannot answer a question frankly and honestly, I will leave my position in Government.

Senator MCCLELLAN. Well, the charge is made that you folks in Government now are under the command or the direction of the administration and you have got to carry out a singsong theme down here and testify. Is that in any way true in connection with you?

Dr. SHANNON. No, sir.

Senator MCCLELLAN. You have spoken freely your own judgments?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. And your own thoughts?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. Without any attempt at being restrained or under any inhibition not to talk freely?

Dr. SHANNON. This is correct, sir.

Senator MCCLELLAN. Thank you.

Senator SCOTT. You are under no obligation toward a consensus then?

Dr. SHANNON. Pardon?

Senator SCOTT. You are under no obligation toward consensus?

Dr. SHANNON. Toward consensus?

Senator SCOTT. Consensus, a famous word.

Senator MCCLELLAN. There is one in the administration who hasn't heard of it.

Senator SCOTT. I am glad.

That is all.

Senator MCCLELLAN. Senator Burdick?

Senator BURDICK. Mr. Chairman, I didn't hear the doctor's opening statement, but I will read is carefully.

Senator MCCLELLAN. Senator Fong?

Senator FONG. Yes, Mr. Chairman.

Dr. Shannon, this question has been very confusing to me, and the matter has been brought up on the floor of the Senate, just from the standpoint of the Government taking the patents. Now, judging from your testimony, you reveal some phases of this subject which are very interesting to me. We have two problems here, as I see it. One, when is the patent completed, up to the time the patent is completed and then from the time the patent is completed to the time that the drug is placed upon the market? As I understand it, the HEW says that if we do have funds in the research, and a patent is completed, the HEW, the Government, takes the patent. Is that correct?

Dr. SHANNON. This is generally correct, sir.

Senator FONG. But the problem is not as easy as that, is it, because here we have the commingling of funds as you have noted in some of these cases where private industry and the Government commingle their funds, and then something is discovered and that is patentable.

Dr. SHANNON. Yes, sir.

Senator FONG. Now, at that stage who takes the patent? Who should take the patent?

Dr. SHANNON. If the invention is made by a PHS investigator at an institution having 1 of our 18 institutional agreements, title is left to the institution for its disposition. But this occurs in only a small number of cases.

Senator FONG. Before we get to that, let's get to the point where we have discovered something.

Dr. SHANNON. Yes, sir.

Senator FONG. The thing is patentable. Who gets the patent?

Dr. SHANNON. Generally speaking, if NIH funds have supported the activity, the discovery is reported to the Surgeon General, and if he considers this a significant advance at his discretion he may——

Senator FONG. Take it over?

Dr. SHANNON. He may insist on assignment of that patent to the Government.

Senator FONG. Now, in your opinion, is that equitable?

Dr. SHANNON. It frequently is not, sir.

Senator FONG. Shouldn't there be a plane of equity here?

Dr. SHANNON. Because, as I pointed out, you may have equal support of the scientist, from the American Cancer Society, and from the National Institutes of Health you have identical patent policies, each saying that you must assign the patent to us. And I think that this puts the scientist in a position where he cannot discharge his obligation.

Senator FONG. You say that the balancing of equities here would be preferable?

Dr. SHANNON. I think there should be some way of balancing equity here, a joint decision.

Senator FONG. Yes.

Dr. SHANNON. As to how the patent shall be exploited?

Senator FONG. Roughly speaking, if the Government puts in 75 percent and private industry puts in 25 percent, there should be a balancing of, say, three-quarters to one-quarter, roughly speaking?

Dr. SHANNON. There should be some way of arriving at a realistic assessment of equity; yes, sir.

Senator FONG. In the discussion on the floor of the Senate as to who owns the patent——

Dr. SHANNON. Yes, sir.

Senator FONG. This is the problem which confronts the Senate. But now we go beyond that. Once we have the patent, then to exploit the patent you say that it requires from $200,000 to $400,000 to really put a product on the market?

Dr. SHANNON. Yes, sir.

Senator FONG. And less than 1 out of 10 do succeed.

Dr. SHANNON. Yes, sir.

Senator FONG. Is that correct?

Dr. SHANNON. Yes, sir.

Senator FONG. So, therefore, if you gave everything to one company actually to put a patentable drug on the market, it would cost about $2 to $4 million?

Dr. SHANNON. No, sir. Let me retrace these figures.

Senator FONG. Yes.

Dr. SHANNON. I said that from the time of the development of a patentable entity, that if one used what success one can have there, one will have success in less than 1 out of 10 cases. That was one statement.

I would say that that one successful case that one develops from the time of discovery to marketing, this will cost $200,000 to $400,000. The others may drop along the way and cost substantially less.

Senator FONG. So it may cost probably $500,000 to $1 million?

Dr. SHANNON. I would think that is reasonable; yes, sir.

Senator FONG. Now, here we have another problem, how to exploit it. If the Government hangs onto it and says it belongs to everyone, nobody will get anything; is that correct?

Dr. SHANNON. This is correct, Senator.

Senator FONG. Usually we find that if everybody owns the thing nobody takes care of it.

Dr. SHANNON. Yes.

Senator FONG. You have got to give it to one person and give him——

Dr. SHANNON. Some incentive.

Senator FONG. Some incentive for doing it.

Dr. SHANNON. Yes, sir.

Senator FONG. And now the question is, how many years do we give him?

Dr. SHANNON. On this, sir, I am not in a position to make a specific recommendation.

Senator FONG. So you just can't attack the problem just from the standpoint of who owns the patent?

Dr. SHANNON. No, sir.

Senator FONG. You have to go beyond that?

Dr. SHANNON. And I don't think you can say any given period of years will satisfy all needs, because in certain cases there may be an extraordinarily expensive development that will take an extraordinary period of time, and I think that any rules or regulations that emerge from legislation, Senator Long, from this committee, should provide for some degree of executive discretion, and I think that the basic legislation should deal with principles of action rather than details of action.

Senator FONG. Yes. I want to thank you very much for your fine testimony. I have been educated this morning. I have been the only Republican voting against the industry, and I want to understand the problem very thoroughly. Thank you very much.

Dr. SHANNON. Thank you, sir.

Senator MCCLELLAN. I just want to make this observation. I don't believe it is possible to write a statute that can do equity in all cases except that a discretion, a major discretion be left to those who administer it.

Dr. SHANNON. I would agree, sir.

Senator McCLELLAN. I don't believe you can write a statute that can foresee and contemplate every circumstance attending a patent and the development of it. I think there must be somewhere some discretion left. As you said in some instances maybe you give them 5 years, in another 2 years, in another something else. I don't know all of the factors that will have to be taken into account and I wouldn't attempt to say, but I don't believe we can write a statute so rigid that it would apply to everything and do justice and equity.

Senator FONG. I agree with you there, Mr. Chairman.

Senator McCLELLAN. Thank you.

Senator BURDICK. Mr. Chairman, in view of the colloquy you had with my colleague, you say that when everyone has the right to a patent that no one will do anything. Would you elaborate on that?

Dr. SHANNON. Well, first I will start by qualifying my comment to Senator Fong.

There are certain things that have such an extraordinary utility in the field of medicine that although everybody has access to it, every pharmaceutical house will attempt to do work on it, and I will mention some examples of these. They are primarily in the antibiotic field. In the case of penicillin, streptomycin, and chlorletracycline, these were wholly new advances where the primary profit to an individual corporate body was to be derived from the extent to which he could refine his processes and make the material more quickly than his competitor. But where the broad use had already been established by the initial observations, we have an example of where everybody had access to the discovery and the licensure, and all of the major pharmaceutical concerns put very substantial dollars into its development. In this case the bulk of those dollars went into process research, and I know this very well because I was in industry at the time. At that time E. R. Squibb & Son—I was director of the Squibb Institute for Medical Research—was the largest producer of penicillin in the country. They were large and had an adequate profit margin because they have very excellent process research. But, at the same time, there were a number of other pharmaceutical houses in it that made this highly competitive.

Now, on the other hand, take a drug that has more limited use at the time it is discovered. Perhaps such a discovery might be made as a result of a series of organic synthesis in a university laboratory, and this is a drug which is shown to have the capability of lowering blood pressure. Well, there already are in existence today a large number of blood pressure lowering agents. No one of these are perfect, but they are good enough to have reduced the mortality rate as a result of high blood pressure roughly 50 percent in the past 5 or 6 years.

On the other hand, many or most of them have fairly serious side effects. Some affect vision, others affect distribution of blood in the body, causing an unstable circulation, and none really gets at the heart of the issue from the standpoint of correcting the fundamental cause of hypertension and truly restores the individual to normal.

Now, from the time that this drug first emerges in the laboratory as a drug that will lower blood pressure to the time that it can

stand up in competition and really be compared effectively with the drugs that are already on the market, this is a period probably of some 3 years' development. And at the initial stage of development one cannot tell whether indeed it will effectively compete with drugs that are already available. In the case of a drug of that sort, for the director of research or the director of development of a given pharmaceutical house to take the gamble and to undertake the development process and undertake the clinical testing and its ultimate establishment as a superior therapeutic agent, an expenditure which in this case would be closer to $400,000 than $200,000, he must be able to show to his board of directors that there is some return in sight.

Now, if this happened to be a relatively simple chemical agent that can be synthesized by any one of a number of pharmaceutical houses, once the use has been demonstrated to be effective, and this becomes known quite generally during the initial stages of a broad clinical exploration, any pharmaceutical house can march in, synthesize the drug and market it in competition with the man who has expended the $400,000 or $500,000 to develop it.

So that unless you can give this man some equity, the chances of him placing his resources at the disposal of this development are very small.

Senator BURDICK. What you are saying, then, Doctor, is that in this field of drugs the American competitive system doesn't work.

Dr. SHANNON. Pardon?

Senator BURDICK. The American competitive system doesn't work as well.

Dr. SHANNON. No, sir; I am not saying that at all.

Senator BURDICK. Well, I mean if discovery X is open to anybody who wants to exploit it, you say it won't be exploited unless one manufacturer or one processor has a special right?

Dr. SHANNON. Sir, I would say that the heart of the American system is the patent system of the United States, and when you administer the patent system so that the innovator, or the man who puts capital at risk can have no assurance of benefit accruing especially to him, you change the financial structure of this industry, so that I do not say that the competitive system doesn't work, but I say that the competitive system has as one of the important elements of it the concept of the possibility of profit as the result of the taking of risk.

Senator BURDICK. What you are saying is that if this discovery is owned by the Government it is available to all?

Dr. SHANNON. Yes.

Senator BURDICK. It won't be developed as well as if some one developer had a special interest in it?

Dr. SHANNON. This is correct, Senator.

Senator BURDICK. Then that does rule out the competitive factor, doesn't it?

Dr. SHANNON. I don't believe so, sir; no.

Senator BURDICK. That is all.

Senator MCCLELLAN. Very well, thank you very much.

Dr. SHANNON. Thank you very much, Senator.

Senator McCLELLAN. In order to accommodate a member of the committee who needs to be at another committee meeting, we are going to skip down and call Dr. John H. Moyer, Department of Medicine, Hahnemann Medical College and Hospital of Philadelphia. We are calling you out of turn in order to accommodate Senator Scott, who needs to be at another meeting as soon as he can get there.

Senator SCOTT. I appreciate it, Mr. Chairman.

Senator McCLELLAN. Sit down, Doctor.

The Chair makes this observation. Apparently our 15-minute rule just simply will not work. I recognize it as quickly as any of you. But we will still undertake to expedite as much as we can, because we do want to hear everybody. As is indicated here at the moment, we are rearranging the calling of witnesses so as to accommodate a Senator who needs to be at another committee, and this afternoon I have to be at another committee so we will do the best we can.

Very well, you may proceed, Dr. Moyer.

STATEMENT OF JOHN H. MOYER III, M.D., PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF MEDICINE, HAHNEMANN MEDICAL COLLEGE OF PHILADELPHIA

Dr. MOYER. Good morning.

Senator McCLELLAN. You have a prepared statement. Do you want to submit it for the record and highlight it?

Dr. MOYER. Yes, I submitted a prepared statement.

Senator McCLELLAN. Proceed, Doctor.

Dr. MOYER. I am John H. Moyer III, physician, professor, and chairman of the Department of Medicine of the Hahnemann Medical College of Philadelphia. I am a graduate of the University of Pennsylvania School of Medicine and I am certified for the practice of medicine in Pennsylvania, Massachusetts, and Texas.

Formerly I was professor of pharmacology and medicine at Baylor University School of Medicine in Texas. As evidence of my qualifications supporting my appearance before you, I am certified by the American Board of Internal Medicine, and I am currently president of the American Therapeutic Society; past chairman of the Medical Advisory Board Council for High Blood Pressure Research of the American Heart Association, and president of the American College of Clinical Pharmacology and Chemotherapy. Additional qualifications are available in my curriculum vitae.

Senator McCLELLAN. You have quite a background.

May I ask you do you own any medical patents?

Dr. MOYER. No, sir.

Senator McCLELLAN. Do you have any interest in any pharmaceutical enterprise?

Dr. MOYER. Yes, sir. I own some pharmaceutical stocks, as many other private citizens do.

Senator McCLELLAN. Very well, let's put that in as background too, because somebody may say you have a personal interest in it.

Dr. MOYER. Right.

Senator McCLELLAN. I have nothing to conceal. Let's get it all out in the open and see if we can't find the correct answer.

Proceed.

Dr. MOYER. Being oriented both by training and experience in the field of clinical pharmacology, which embraces the study of new drugs, I should like to make a number of points as to how the proposed changes in Government patent procedures might alter these activities in medical schools such as the Hahnemann Medical College.

I should like to point out at this point that in my presentation I don't mean to get into the legal technicalities of this consideration whatsoever but merely to present my points of view as an academician which I believe gets me out of the patent problem in so far as my own personal interests are concerned.

First I should like to emphasize that the study of new drugs in man is referred to as the science of clinical pharmacology, an emerging scientific field of ever-increasing importance. This involves the administration of chemicals, i.e., new drugs for the first time to patients which requires considerable knowledge and experience on the part of the physician who does this. Of necessity such clinical studies are usually done in academic institutions, that is, the administration of drugs to patients for the first time, where multiple skills are available in the various subspecialties of medicine and which are needed to assure maximum safety to the patient when drugs are used for the first time in man.

I might indicate that, for example, in our department we have subspecialties of endocrinology, clinical pharmacology, vascular diseases, cardiology, and the like. There are some 14 subspecialties represented by separate subsections of our department of medicine.

This collaborative effort in research on new drugs includes investigators who are proficient in basic biochemical information as well as the clinical subspecialties, that is, those who have a comprehensive knowledge of clinical medicine. This resource of trained personnel is an absolute requirement for the development of new drugs, since availability of biochemical agents on the shelves of the pharmaceutical companies is valuless unless the use for such agents can be found for the treatment of specific human illnesses, pointing out the fact here, of course, that biosynthesis is an initial phase of the development of a new drug but certainly is a long shot making the drug available for use in patients.

Senator McCLELLAN. What is that?

Dr. MOYER. The availability of chemical agents is far from the use of such agents in patients for the treatment of illnesses.

Senator McCLELLAN. I follow you.

Dr. MOYER. I think that it is important to emphasize these points because of the great advances in the development of new drugs over the past 10 years which have thrown a strain on the facilities, personnel, and equipment of academic institutions. Although the Federal Government has seen fit to support some of these activities, it has by no means supported the major share of the clinical evaluation of new drugs to date. It is essential that a cooperative program exist between the source of these drugs, that is, industry, and the academic institutions as well as the Government.

I might add at this point that of the drugs being used today, the majority of these were not available in 1950 except for some 12 or 15, perhaps basic drugs. Most of the drugs that were available when I first became interested in research along this line have now been altered in such a way as to be either more effective or entirely new agents for the treatment of disese have been developed.

To attempt an effective program of drug research and development in any other way than this cooperative venture in my opinion disturbs a relationship that has been so important in the medical advances of the past 30 years, and would be to the serious detriment of medical development in the area of patient care and the treatment of human ills.

I take now an example as it involves our institution.

Our Department of Medicine at Hahnemann Medical College initiated more than 100 research projects during the 1964–65 fiscal year. Although the total number of research dollars received from the Federal Government was greater than that received from private sources, the number of individual projects supported by non-Federal sources exceeded those supported by the Federal Government, a large number of these coming from pharmaceutical industries. In fact, over the past 5 years, we have worked with over 30 different pharmaceutical firms, studying different, new drugs. The very fact that one department of a single, medium-sized medical school composed of only 37 salaried physicians has a multiplicity of grants from the Federal Government as well as from industry, indicates the desirability and in fact the necessity of many of our personnel participating in a variety of projects variously supported when new drugs are being evaluated.

In other words, many of our personnel may receive portions of their salary from different sources. Perhaps they are working on one project, as basic project supported by NIH, 10 percent of their time, and then 10 percent of their basic salary is received from the National Institutes of Health.

On the other hand, that same individual may spend a portion of his time working on a new drug which obviously may lead to new development, and, of course, you see immediately the overlap within one individual or one investigator as to source of support.

Furthermore, the flexibility of these funds received from private sources for support of research should be borne in mind, because frequently you can get small grants for a new idea, and this can be arranged for within a matter of weeks, at least no longer than a month in many cases. Whereas the machinery of government is such that the shortest period of time is in excess of a year for support of a new concept from application to funding, at least by the National Institutes of Health. It is obvious then that if a Government patent policy exists claiming rights for the Government from all projects touched by Government money, collaborative research could not exist, and it would probably be impossible for a department, such as ours, to continue in the evaluation of new drugs, because we are supported so heavily from Government that we obviously coudn't forgo Govern-support. This would then block our participation in the minor area of non-Federal support of our program. Although from an applied point of view our contributions toward the health of our citizens is greater in the latter than in the former.

Since the same individual participates in two research projects, one would obviously have to go if patent procedures militated against this individual participating in both programs.

The source of nearly all new drugs is from private industry, and if industry is not able to bring about this trial of their new discoveries in patients, the results are obvious, I think.

By what I have already stated, I do not wish to indicate that the current status of patent rights as they relate to the development of new drugs should not be carefully evaluated. However, in my opinion, a clear delineation should be made between support received by the academic institution from the Government as research grants-in-aid and moneys received in the form of contractual arrangements for the specific development of new uses or of new inventions, which would include new drugs. The financial structure of most of our academic institutions is such that if the Federal Government claims patent rights for new drugs developed in those institutions receiving grants-in-aid in any form—again I differentiate grants-in-aid versus the contractual arrangements with Government, that is noncontractual research support—then it would make it impossible for most such institutions to continue to excel in the clinical pharmacological area; i.e., the development and clinical trial of new drugs. On the other hand, when support is received from the Federal Government through specific contractual arrangements for support of a research project and patent rights are involved on these specific projects, then the details can be negotiated and drawn up beforehand so that they are well understood by all, and an equitable arrangement can be arranged. This allows the institution to select and delineate and thus avoid conflicts of interests. To achieve these objectives, the right to negotiate must exist and flexibility in such negotiations is required.

The third point that I should like to emphasize, but that actually revolves around points 1 and 2 above, is the great desirability of cooperative venture among industry, the academic institution, the Government, and I think that this is very important. I have a very personal feeling about this, and the cooperative venture between the various personnel involved, the last of which is a commodity which cannot be purchased at any price. For example, it is not uncommon for our academic people who receive part of their support from the Government, part from the institution, and part from private industry, to sit down at the conference table, as representatives of the three parties, not only different representatives but many times the same individual may represent more than one party, to discuss common problems in therapeutic research. This leads to maximum originality and the development of cooperative ideas.

I think we should recognize that to date most developments are cooperative ventures involving many scientific minds. Very few of them result from individual endeavors; it is a team approach rather than an individual any more. Therefore, it would be a blot on our scientific endeavor should it become impossible to continue this cooperative venture, purely because of inept patent rights considerations.

I would emphasize here that monetary considerations which might accrue to the Government or be secured by individual citizens through nonexclusive patent rights would be relatively unimportant as com-

pared to the havoc that would be done through the destruction of the cooperative relationship of highly trained and experienced personnel among academic institutions, private industry, and Government, which presently exists.

Next I might paraphrase here Shakespeare, as to, "Is it not better to allow above-average compensation for an outstanding discovery than not to have discovered at all?"

I should now like to touch on the problem of inventions versus application. The two are not the same as it relates to us. In fact, a medical school's involvements in research, particularly in the field of clinical pharmacology, is primarily related to development and evaluation, and not to discovery and invention.

Nearly all of the pharmaceutical agents which we have evaluated have been developed by private industry as biochemical agents, coming out of major screening programs which would not be feasible in an academic institution. This is when 50 technicians, shall we say, can be set up for a technique of studying a drug which perhaps blocks the contraction of the smooth muscle in the intestine. A thousand drugs are then run through such a screen searching for an effective compound. An academic institution rarely would take on such a proposition. This, of necessity, comes from industry.

Then after the drugs are screened and developed, it becomes our responsibility in the medical schools around the country, based on our knowledge of drugs and their effects on patients, to evaluate their potential properties as therapeutic agents before they are ever given to large numbers of patients. If in this evaluation the drug does have a potential usefulness without undue toxicity, it is then evaluated as to its pharmacodynamics and its effectiveness in the treatment of human ills. That is, it is administered to increasingly large numbers of patients. It should be obivous that confidence must exist between the academic institution and the source of the drug as to the integrity and correctness of information.

Finally, I would like to comment that this whole problem, and I am sure this is not an original statement, is not simple. In fact it is rather complex as viewed from our point of view as a private institution such as ours faces its research problems, especially those related to multiple sources of financial support.

The orientation on patent policy, it seems to me, is now based as far as I can tell, upon equitable interests, and should be continued. I must say even the current NIH policy I think does in a minor way perhaps discourage the development of some new concepts that would be patentable.

For example, when the Government contracts and pay for a specific project, the Government should have the patent right to inventions leading from that project, in my opinion. But where there has been cooperative investment, the rights of each cooperative party should vary according to his contribution. If industry supports 50 percent, or shall we say 33⅓ percent, the institution 33⅓ percent, and the Government an equivalent amount, I should think that the equitable interest would be equivalent to all three parties.

Unfortunately, we cannot express a predetermined formula which spells out the equities of each project. We believe that equitable in-

terests of the contributing parties can only be protected by a flexible policy.

Senator McCLELLAN. Very well, Dr. Moyer, thank you, sir.

Senator Scott, do you have any questions?

Senator SCOTT. Dr. Moyer, I would like to have you give me an answer to this. How can we best achieve the objective of preserving the team effort of the Government and private sectors in developing drugs and medicine? And I mention the alternative, by granting discretion to the Secretary of HEW to acquire or waive patent rights on a case-by-case basis, or by limiting the discretion in favor of granting exclusive rights to the private contractors, or by some other alternative.

What is your conclusion as to what you believe would be the fairest solution?

Dr. MOYER. If I understand you, Senator Scott, you gave me two alternatives. One of them——

Senator SCOTT. One is based on one bill before us and the other is based on the other bill; that is correct.

Dr. MOYER. I do not mean to get into the technicalities of the bills, although I have read them very carefully—in my opinion, the law should be set up so that equitable rights of the participating parties can be honored, and I would see no reason, as of the moment, why the pharmaceutical firm in the development of new drugs would be any different than any other development—shall we say the development of hardware for computerization of research. On that basis, then, I would think that if the Government supported completely, for example, the research of a new drug for the treatment of hypertension, then they should own exclusive patent rights and handle them appropriately.

On the other hand, if the Government supported a research area in part for basic research, and these people finally also participated in the development of a new use or a new agent but that work was entirely supported by industry, then industry supporting that project should have those exclusive patent rights.

I don't know if that is——

Senator SCOTT. It is a difficult question to answer, in any event.

I am trying to recall the testimony of Dr. Shannon as to the advisability of granting a period of exclusivity.

Dr. MOYER. You mean insofar as the length of the patent right?

Senator SCOTT. Yes, I will read it.

Dr. Shannon said:

One possible solution might be the granting of short periods of exclusivity in such situations—

As he was discussing—

that is where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industry cooperation.

Would you comment on that?

Dr. MOYER. Well, I would think that this would be appropriate. For example, if the Government did support a new development, a new use, or a new agent, then I would think that they should have the patent rights and they should handle the situation as they can

best develop the new drug. If this is an agent which does not have significant monetary return, then I should think that the Surgeon General, or an agent of the Government responsible for this, should set up exclusive patent rights for a company so that the company in question could get adequate return on their money for the development of this drug.

The development of this drug may require a much greater financial outlay, according to our current Food and Drug Administration requirements, than they did in the past. For example, we may have a chemical agent which we could predict, having used in animals, that it has a certain use for the treatment of multiple sclerosis. If there was such a drug, it would have a limited application. We know that beforehand. So that we couldn't expect to sell this drug for use on millions and millions of patients as we could a drug for the treatment of heart failure. This would have to be recognized, and this would require, I think, some exclusive patent rights or licensing to an individual or company, if the manufacture of the drug were to be feasible. This feasibility, I think, could be financially calculated on the basis of, first, the use of the agent; second, its effectiveness; and third, how much more be required from the toxicity point of view to make this available for the treatment of patients with multiple sclerosis.

With that information, then, you could calculate roughly what would be required, as far as exclusive patent rights are concerned, to let that drug go as an exclusive patent to a company for a limited period of time, say 3 to 5 years.

Senator SCOTT. I gather you feel that unless there is an incentive to industry as contemplated by the patent system generally, it would be most difficult to persuade industry to cooperate in carrying out further development of new discoveries or improvements upon old discoveries?

Dr. MOYER. I speak much as a layman here, Senator, but I can say one thing. If you don't have incentive, either to a group of individuals or to an individual himself, they aren't likely to do very much; is this not correct?

Senator SCOTT. Well, I think it speaks for itself.

Dr. MOYER. So that I think we have to recognize in our system that industry is set up to make money. The board of directors of a company, when they make investments as representatives of the stockholders, and they are obligated either directly or indirectly to take such steps as are needed to make money.

Now, in a particular drug, for example, this drug may not itself reap a large financial return. But the company may have other objectives such as the broad spectrum of available drugs for a certain group of diseases which that company wants to become known for. If given some guarantee that they won't lose money, the company may take on the chore of developing a new drug even though the company knows it won't make much, either. I speak now of drugs with limited sales. Such a drug could be a life saving commodity, even though needed infrequently.

Senator SCOTT. We lawyers have a phrase, where the property of a number of people has been mixed so that it can no longer be identified, we refer, for example, to wheat in the grain bin which belongs to a

number of owners and you cannot tell which owner really has which grains of wheat, and that is known as fungible funds.

Now, here the money contributions to research have in a sense become fungible. You can't really tell which contribution is from private industry, which by the Government, is being applied in exact proportion to fundamental research in the fundamental cause and cure of disease, let's say. It seems to me that is one of the most difficult problems to work out in legislation, and I belive you have expressed your views on it, and that is what concerns me just about as much as anything in the bill.

Dr. MOYER. I am in complete agreement with what you said. I think there are two points that I might emphasize. One of them has to do with the current method of NIH support. They do require a breakdown of each basic research project, in which salaries are involved, and require an estimate of that portion of the salary being supported by the Government based on the percentage of time the individual spends on the project. So, if you participate in a research project 10 percent of your time, this is identifiable according to current support as 10 percent of the investigator's salary. Thus any individual receiving part of his salary for the conduction of a Government-supported research project does, in effect, become Government supported. Such an individual working part time for a drug house on a new drug would jeopardize the patent right for that company. As you can see, this would preclude any investigator who receives partial salary support from his Government research project from doing investigation on new drugs for private industry.

Another point I would make is that there is no great difficulty when you are supporting a specific research project in identifying the priority of patent rights. But frequently from parent research projects come a number of throwoffs which are merely ideas, and I don't think you can even corner the market on these. Just like I can't control your ideas and what you think about what I might present to you, so I don't think that you could ever confine by legislation the ideas and concepts of an investigator, irrespective of his support.

Senator SCOTT. That is all.

Thank you, Mr. Chairman.

Senator MCCLELLAN. Senator Burdick.

Senator BURDICK. Just one comment to make concerning your colloquy with Senator Scott.

You say that the incentives of a group and the incentive of the individual himself is very important.

Dr. MOYER. Yes, sir.

Senator BURDICK. I noticed you have on your staff 37 salaried physicians, according to your statement on page 2. You must have a considerable number of scientists on your staff also.

Dr. MOYER. I hope they are all scientists.

Senator BURDICK. I mean you have some that are categorized as physicians that are probably Ph. D.'s in some field of science, too.

Dr. MOYER. In that group I think there are only four or five Ph. D.'s. The others are M. D.'s, and I would say that all but two of these fellows participate in research projects. The reason those other two do not is their primary responsibilities are organizing our medical school teaching programs.

Senator BURDICK. This statement intrigues me. Here you have a group of men who spend a large part of their lives in training their minds in this field. We talk about commingling Government money. We talk about commingling industry money. But we forget entirely about the human element here, the ideal that comes out of that human mind.

Dr. MOYER. Right.

Senator BURDICK. Does your institution ever give any patent rights to that scientist who himself finds the discovery?

Dr. MOYER. We have an arrangement with Research Corp. I can't give you the exact details, but it goes somewhat as follows: If the investigator gets an idea, and we have had three such cases occurring in my department in the last 4 years, if an investigator get a new idea which he thinks can be patentable, then he comes to me. Of course, not being knowledgeable in the details of these things, I send him up to President Cameron, who is responsible for this sort of thing, as far as our institution is concerned. The institution then has this reviewed by Research Corp., and, if it is decided by this more knowledgeable group that this indeed should be followed up, then an arrangement is made with Research Corp. in which they get a monetary return on the net proceeds; i.e., the royalties. The institution receives an amount, and they in turn can arrange with the individual investigator so that he receive some of the royalties. In fact, this happens to be President Cameron's policy. When an individual would, in fact, become responsible for the development of a new agent or a new use would come to fruition, then the individual would benefit in part from that development.

Senator BURDICK. Have any of your doctors or professors benefited so far from your research contracts?

Dr. MOYER. No, sir. There is one pending that could potentially develop.

Senator BURDICK. But your opinion is that, if the project is identified as a Federal project totally, then the patent right should go to the Federal Government?

Dr. MOYER. Yes, sir. I am removing the individual investigator, as referred to above, from consideration.

Senator BURDICK. It is only in this case where the interests and efforts are mixed where you think there should be some equitable solution?

Dr. MOYER. Yes, sir.

Senator BURDICK. Thank you.

Dr. MOYER. And I might add that I am particularly interested in our basic support. I mean, I am particularly concerned that finances coming in for basic research, in which this comes into the same institution or same unit in the institution, the same department or even to the same individual who might also be working on developmental type research, that the fact that he receives support from the Government for his basic research does not prohibit his also participating in applied research; that is, the bringings of new drugs to fruition and use in the treatment of patients.

Here I think is the real potential harm, because, while the Government itself is trying to develop clinical pharmacology units, I can see

a barrier being set up in which, unless the whole industry was socialized, would block industry from having their drugs studied in any institution receiving this type of Government support.

Senator BURDICK. Thank you.

Senator MCCLELLAN. Thank you very much, Doctor.

Dr. Sprowls and Dr. Bliven, will you come around, please?

Gentlemen, will you identify yourselves and proceed?

I believe you have a statement. Is it a joint prepared statement?

STATEMENT OF JOSEPH B. SPROWLS, CHAIRMAN, EXECUTIVE COMMITTEE OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; ACCOMPANIED BY DR. CHARLES W. BLIVEN, EXECUTIVE SECRETARY

Dr. SPROWLS. Sir, I have a statement which I am presenting for the Executive Committee of the American Association of Colleges of Pharmacy.

Senator MCCLELLAN. Very well, you may each identify yourselves for the record, and then proceed.

Dr. SPROWLS. I am Joseph B. Sprowls. I am professor of pharmacy and dean of the Temple University School of Pharmacy, and a registered pharmacist in Pennsylvania, Colorado, and New York.

I have been a teacher of pharmacy for nearly 30 years and have held full-time faculty status in three universities: the Universities of Colorado, Buffalo, and Temple University. I appear here as the chairman of the executive committee of the American Association of Colleges of Pharmacy. This is an elective position.

I have with me Dr. Charles W. Bliven, executive secretary for the association and formerly dean of the School of Pharmacy at George Washington University.

Senator MCCLELLAN. That identifies both of you sufficiently.

You may proceed.

Dr. SPROWLS. All of our 74 member colleges are engaged in scientific research, much of which derives some support from Federal granting agencies and some of which derives support from private sources, including industrial laboratories. Our interest in patent legislation derives from the research efforts of our member institutions.

We commend the Congress for its interest in new patent legislation, because certain clarifications are needed both for the protection of the proper interest of the public and for the clarification of the rights of inventors when public funds may have been involved in some phase of the development process.

We believe that the protections afforded by the present patent system to the inventor or the primary developer of a new and useful concept are quite important both because they help to stimulate the investment of private capital which provides major and essential support for the research and development efforts in our country, and because they provide the incentive for the initial production and distribution, without which the benefits of invention can never reach the ultimate consumer. We submit that these incentives are important in furthering the development, testing, and production of pharmaceuticals as well as all other useful products. We feel, therefore, that the best

interests of the public will be served by legislation which is neither discriminatory nor confiscatory and which permits an equitable arrangement for patent ownership with institutions which have made major contributions to patentable discoveries.

We believe that preemption of rights to inventions by the Federal Government should take place only in unusual instances where national security, public safety, or the health of the public demand, or when Federal funds have contributed in a major way to the development of the invention.

While research in academic institutions is not ordinarily undertaken with patent motivation in mind, it is, nevertheless, true that one of the benefits which occasionally derives from such investigation is an invention which has widespread utility or applicability. When such inventions do arise, it is usually necessary to secure a patent in order to obtain the interest of organizations which are equipped to produce and distribute products and to thereby make the benefits of the invention available to the public.

We would point out that many educational institutions have adopted policies which are designed to prevent abuses of the patent system and which provide for an equitable distribution of benefits between inventor and parent institution. In many instances provision is made for a considerable portion or all of the royalties collected on a patentable invention to be utilized in the support of further research. In general, these policies are designed to preserve the unselfish approach of the investigator as well as the public-spirited philosophy of the university.

We believe that some of the legislative proposals now under consideration do not provide proper recognition for the contribution which the institution and the investigator may have made in a particular instance. One proposal suggests that if any portion of the support has come from Federal sources, patent rights may be assumed by the Federal agency. Yet the particular research project may be the culmination of many investigations carried on by a scientist or his department. Furthermore, concepts do not usually emerge from a single research project but may represent the product of many investigations and a great deal of study and preparation on the part of the investigator. We believe that it is in the best interest of the public to make certain that contributions of institution and researcher are recognized in the assignment of patent rights.

The colleges of pharmacy have a particular interest in research which is related to public health, in particular that phase of research which is directed toward the development of new therapeutic agents. This research is often supported by, and/or coordinated with, research conducted by pharmaceutical manufacturers. For example, an investigator may synthesize a new drug, but he is usually in no position to carry it through the development and production procedures which are necessary before it can become available for public use. In fact, the university investigator is and should be more interested in the basic phase of the research, not in its application. Many departments have solved this problem by making arrangements with a pharmaceutical manufacturer for the conduct of the testing and development procedures. The preliminary screening of drugs is normally done

without charge by such companies in order to assist investigations in which they have a particular interest or capability. Passage of legislation such as section 4(a)(2) of S. 1809 would greatly lessen the probability of such cooperative arrangements. In fact, member colleges have already encountered difficulty in making arrangements for the testing of drugs when Federal funds have been involved in the research leading to their discovery. Unless a more equitable policy can be formulated, we foresee the development of a barrier between industry-university research which we believe is undesirable and not in the interest of the health of the public.

Approximately 75 percent of the financial support for research in member colleges now comes from Government sources; thus, we can conclude that more than half of all projects have been supported to some extent by Federal funds. It is unlikely that industrial laboratories will be interested in cooperating with such projects if it will be impossible for them to recover investment or to insure continued funding of operations through the marketing of a patent-protected invention. We believe that it is in the interest of progress to encourage cooperation between industry and university with the understanding that the university is primarily concerned with basic research, the industry primarily with its application.

Such considerations lead to the conclusion that section 4(a)(2) of S. 1809 should be modified in such a way that inventions in the health field may be treated in the same manner as inventions in all other fields. In this way the incentive to bring promising inventions from the research laboratory to the public as completely tested and fully developed dosage forms will be accomplished in an expeditious and efficient manner. Thus will the best interests of the health of the public be served.

Dr. Bliven and I appreciate the privilege of being heard on behalf of the American Association of Colleges of Pharmacy and we will be pleased to answer questions.

Senator McCLELLAN. Is that the only objection you have to S. 1809?

Dr. SPROWLS. Sir, we feel that 4(a)(2) is somewhat ambiguous.

Senator McCLELLAN. Which one?

Dr. SPROWLS. 4(a)(1) is somewhat ambiguous, also, but we were primarily concerned with the matters relating to public health and the possible interpretation of this in terms of pharmaceuticals.

Senator McCLELLAN. What would you suggest in lieu of subsection 4?

Dr. SPROWLS. I would suggest something along the line——

Senator McCLELLAN. Have you got any language you would suggest?

Dr. SPROWLS. I might say, Senator, I am not a lawyer. I, too, am a technician. I can only speak in——

Senator McCLELLAN. I am not trying to argue with you.

Dr. SPROWLS. No, I understand. I was just going to say that I couldn't possibly give you the proper language. I can only give you a philosophy. I believe that 4(a)(2) could be interpreted to mean that all drugs, or the patent to all drugs, must pass into the hands of a funding agency, of a Government agency, if there was any Federal funding involved, and if this is what it means we believe that it should

be modified so that an equitable distribution of the patent rights could be made.

I am not prepared to give you exact language, but I am prepared to state my philosophy about it.

Senator McCLELLAN. Have you any comment as to the other bills before the committee?

Dr. SPROWLS. I think, sir, that the language as contained in S. 2326 in this section is somewhat better.

Senator McCLELLAN. This is a bill that has just been introduced?

Dr. SPROWLS. Yes.

Senator McCLELLAN. I haven't had an opportunity to study it. You would suggest the language in——

Dr. SPROWLS. I think the language in S. 2326 is——

Senator McCLELLAN. You mean on page 5?

Dr. SPROWLS. Yes.

Senator McCLELLAN. Section 4?

Dr. SPROWLS. Yes. I think it is more explanatory.

Senator McCLELLAN. You think that language is better and preferable to the same section, section 4 of S. 1809?

Dr. SPROWLS. I think that in general it is somewhat more understandable.

Senator McCLELLAN. You may be correct in that. I wouldn't argue that.

I would like to get any specific suggestions that you folks have, because we might very well overlook something which you technicians would immediately recognize as being defective or not actually accomplishing what the author would like to accomplish or what the committee might like to accomplish.

Dr. SPROWLS. Much of what I would like to say was said by Dr. Shannon and by Dr. Moyer to the effect that we must have an equitable arrangement of some kind to recognize that many contributions have been made in the average invention. The institution has made a contribution. The inventor has made a contribution. The Federal funds represent only a part of the contribution, and if the patent is to become exclusive property of the Government I foresee all of the difficulties which were mentioned by Dr. Shannon with respect to bringing that invention to the ultimate users.

Senator McCLELLAN. Thank you very much.

Senator Scott, any questions?

Senator SCOTT. No, I have no questions.

Senator McCLELLAN. Senator Burdick?

Senator BURDICK. I am quite amazed at your statement. You say based upon—what do you call it, philosophy?

Dr. SPROWLS. Yes.

Senator BURDICK (continuing). That you don't feel that public money spent for public health discoveries made thereunder should belong to the public.

Dr. SPROWLS. I don't believe that I said that, sir.

Senator BURDICK. Well, that is what 4(a)(2) refers to, directly concerned with public health.

Dr. SPROWLS. Well, I hope I haven't said that we should give no consideration to the funds spent by the Government.

Senator BURDICK. I said should have exclusive rights for the expenditure of Government funds on public health. You say no.

Dr. SPROWLS. I say we must have an equitable arrangement which recognizes the contribution made by an institution or by an individual or even by a second funding agency.

Senator BURDICK. Even when it affects public health?

Dr. SPROWLS. Yes; certainly.

Senator BURDICK. That is all.

Dr. SPROWLS. I believe that we serve the best interests of the public health by making certain that these inventions come to the public.

Senator SCOTT. Mr. Chairman, may I make one comment here with all due respect to my colleague?

I might point out an illustration where the Government spends a good deal of public money where the benefit of the money is not controlled by the Government, where the Government has very little to say in the final analysis as to how it is spent, and that is in the present poverty program.

Senator MCCLELLAN. Very well. Thank you.

Mr. McKie?

Mr. McKie, please identify yourself and then you may proceed.

STATEMENT OF EDWARD F. McKIE, JR., ON BEHALF OF THE AMERICAN BAR ASSOCIATION

Mr. MCKIE. I am Edward F. McKie, Jr., an attorney in private practice in this city. I am here on behalf of the American Bar Association of which I am the vice chairman of its section on patent, trademark, and copyrights.

I do not appear here on behalf of any client, but rather only for the association in support of the beliefs which I hold in common with the association as to what is in the best interest of the public in this area.

I do have a printed statement, Senator, which I think you have a copy of. I would ask that it be printed in the record, but I do not intend to read it. I would prefer rather to highlight it.

Senator MCCLELLAN. Very well, your statement may be printed in the record in full at this point, and you may highlight it and make such other comments as you wish.

(The prepared statement referred to follows:)

STATEMENT OF EDWARD F. MCKIE, JR., ON BEHALF OF THE AMERICAN BAR ASSOCIATION, WITH RESPECT TO S. 2326 BY SENATOR DIRKSEN, RELATING TO GOVERNMENT PATENT POLICY

I am Edward F. McKie, Jr., in the private practice of law in Washington, D.C., specializing in the field of intellectual property. I am the vice chairman of the Section on Patent, Trademark, and Copyright Law of the American Bar Association and the chairman of the committee on legislation of that section. I appear here on behalf of the American Bar Association to supplement the testimony of Tom Arnold, now past-chairman of that section, delivered to this subcommittee on June 2, 1965, in respect of several bills dealing with Government patent policy. At that time Mr. Arnold explained the reasons of the American Bar Association for opposition to the various bills then pending. Since that time Senator Dirksen has introduced S. 2326 which is consistent with the beliefs of the American Bar Association as to an equitable and effective Government patent policy in the public interest. We, therefore, asked for an opportunity to appear again before

this subcommittee to supplement the testimony given by Mr. Arnold on June 2, in order that we might express our positive approval of the principles embodied in S. 2326.

To supplement only, because Mr. Arnolds' testimony is as well applied in favor of the distinguishing characteristics of S. 2326 as it is against certain features of the other bills now being considered by this subcommittee. The principal features of distinction between S. 1809 (McClellan) and S. 2326, as emphasized by Senator Dirksen in introducing the bill, are the following:

(1) Under S. 2326, no citizen of the United States could be deprived of a royalty-free license in any patent owned or controlled by the United States; and

(2) Under S. 2326, the Government can require an interest greater than a royalty-free license only in certain limited situations where the public interest justifies it.

Referring first to the second feature of distinction, it should be recognized that nearly all governmental research and development contracts may involve in some way the public health, welfare or safety. S. 1809, in its requirement for acquisition by the Government of the exclusive rights in any invention made in "exploration into fields which directly concern the public health, welfare, or safety" therefore raises the strong possibility that ownership by the Government of the right to exclude the public from the use of most inventions made in Government-sponsored research would result. Particularly when it is appreciated that many inventions are made as byproducts of the research being undertaken, and not as the object of that research, the result of Government ownership in such a high proportion of cases is believed inequitable.

The most important distinction of the Dirksen bill, however, resides in the limitation which it provides on use by the Government of the right to exclude granted by patents. This limitation is founded on the belief that the Government should never be permitted to take the exclusive right to an invention for the purpose of excluding its citizens from the practice of that invention. Rather, in the event it takes that right, it should be only for the purpose of preventing exercise of the exclusionary right to impede the free use of the invention by any citizen of the United States.

The consequences of the Government acquiring and enforcing against its citizens the right to exclude have been well brought out by Mr. Arnold and need not be repeated. However, his point that the patent right is not the right to use an invention bears repetition for it is so seldom appreciated. It must be realized that, no matter who takes title to the patent rights on inventions arising from Government-sponsored research, the Government will have the right to use those inventions. The patent right cannot control that use, though it can control use of the invention by nongovernmental entities. Its acquisition by the Government can give rise to Government control over private industry to an extent now impossible unless the implementation of that right to exclude is foreclosed by the Government.

The American Bar Association believes that S. 2326 is in accord with principles which it believes are in the best interest of the public. It therefore recommends enactment of that bill, or at least amendment of S. 1809, in the respects by which the Dirksen bill differs therefrom.

Mr. McKie. Thank you, sir. Of course, the American Bar Association has already appeared in these hearings on June 2 in the person of Tom Arnold, who at that time was chairman of our patent section. The reason for requesting to reappear is that at that time Mr. Arnold testified in the negative, essentially, with respect to certain of the bills that were then pending. That is, he criticized some aspects of these bills.

In the interim a bill has been introduced by Senator Dirksen, S. 2326, which is the other side of that coin. It is the positive approach, which is based on the principles which Mr. Arnold expressed. For that reason we asked to come back and explain our reasons for being in favor of the Dirksen bill.

There are two prime differences between the Dirksen bill and S. 1809, upon which of course it was primarily based. Those two dif-

ferences are in respect of Government ownership in the area that was just pointed out by the last witness, that is with respect to section 4(a)2 of S. 1809, that is the field of public health, welfare, or safety, and the second aspect as an respect of what the Government shall do with whatever patent right it has.

We feel that 4(a)2 is so broad that much if not most of the Government research money could be said to be spent in furtherance of the objectives of public health, welfare, or safety, and that as a result much of the patent rights or inventions developed by Government research and development money may go to Government.

Remembering that the patent right is the right to exclude and not the right to use at all, we are concerned about the use of this right to exclude by the Government to foreclose its citizens from the use of inventions developed with public money. So that these two principles are intertwined.

We think that section 4(a)2 is somewhat too broad in this respect, and prefer the approach expressed in the comparable section of the Dirksen bill in that area. Also we think that the Government should not attempt to exclude its citizens from the use of inventions made under the support of public money.

Senator McCLELLAN. What do you mean exclude them from it? We are trying to find a way to get the inventions out to the ultimate consumer, for the benefit of the public.

Mr. McKIE. Right. The patent right is the right to exclude, however. We think that the Government has no need to have that right to exclude.

Senator McCLELLAN. In other words, the Government shouldn't take the patent?

Mr. McKIE. That is right.

Senator McCLELLAN. That is what you are trying to say.

Mr. McKIE. That is right, Senator. In general, that is true, Senator. There are some areas in which the Government may feel that it should have the right to exclude, and these are also comprehended by the Dirksen bill.

Senator McCLELLAN. Let me ask you this question. You name the disease. Suppose that you haven't found a cure for it yet, and the Government goes to some institution or pharmaceutical research center and says, "We want you to concentrate on this. We will give you a contract. Here is the money. We will finance it. Spend what you need until you find a drug that will be beneficial in the treatment of this particular disease. It will be a cure for it."

And that institution or that pharmaceutical house does that. The Government puts all the money in there. Do you not think the Government then should own the patent?

Mr. McKIE. No; except in limited circumstances.

Senator McCLELLAN. Do you think the private sector should own it?

Mr. McKIE. Yes; that is right, Senator. I think for the reasons—

Senator McCLELLAN. Even though the Government's money paid for all of it?

Mr. McKIE. That is right, Senator. I would again emphasize that this is the right to exclude. It is not the right to use the invention that we are talking about. The public is going to have whatever benefits derived out of the discovery of this invention.

Senator McCLELLAN. I don't know. There is some testimony here to the contrary. You discover an invention and then unless someone processes it and unless somebody refines it and tests it and experiments with it to bring it to that stage of human use and human benefit, there is no benefit.

Mr. McKIE. That is another aspect of the same thing, I think, Senator.

Senator McCLELLAN. It is part of the same thing, I known.

Mr. McKIE. Yes.

Senator McCLELLAN. All right.

Mr. McKIE. I think we are talking about a number of different things intermixed here. One, and I would like to emphasize this, the patent right is not a panacea. This is not the thing that causes all inventions to come to use by the public. It is one aspect only.

Senator Long, in some remarks on the Senate floor, has referred to a number of inventions that were brought to use by the public without any patent rights whatsoever. There are such inventions. This was indicated today also by other witnesses.

However, there are some inventions, we think a number, in which the patent right, the right to exclude is important to give an initial period of protection. Now in such case we think that the person who should get that is the person who discovered the invention or his assignee.

Senator McCLELLAN. I think I agree with you on this. Where the Government under the conditions I have illustrated, a discovery is made and it is patented, at that stage I would think that the Government should own that patent, if all of the investment that went into it was taxpayers' money. I may change my mind about this but as of now I am under that impression.

Now the thing is patented, that is the idea is patented, so to speak. But from there on there has to be risk capital for investment as has been testified to here, of from $200,000 to $400,000, and even maybe much more, before it can be developed and tested and refined and put into a process for marketing.

Now to get that done, the Government is not in a position, it doesn't have the facilities, then why shouldn't it make a contract with someone who is in a position to do that, to take the risk and give it some incentive in the way of a license for a given number of years, an exclusive license for a given number of years or a requirement for licenses to competitors at a fixed price or some fixed consideration, to make certain that the benefit actually flows to the public.

Mr. McKIE. I am answering that this way if I may. That I think necessitates the willingness of the Government to sue its citizens for infringement of its patents, because you cannot force people to take a royalty-bearing license unless you are willing to sue infringers.

Senator McCLELLAN. I think the licensee would be the one probably to bring the suit. But you are not sure that it is valid. But you have got the patent.

Mr. McKIE. Well, he would have to bring the suit with the use of the name at least of the patentee under our present laws.

Senator McCLELLAN. It would be the infringement of a license granted by the Government as well as a patent granted by the Government.

Mr. McKie. Technically no, Senator. You would infringe a patent but you would not be infringing upon a license. If, however, an exclusive period should be granted, it seems to us that it is preferable that it be granted to the person who has an interest in the invention initially.

Senator McClellan. I would agree with that. I agree that the choice preference should go to him who developed the invention.

Mr. McKie. Then I think we are going around the barn to come back to the other side.

Senator McClellan. It may be.

Mr. McKie. If you leave the right originally with the person who made the invention, he has the most interest in that invention of anybody in the world at that particular time, he is more likely to bring the invention to the public and exploit it.

Senator McClellan. I agree with that. There is, and I can't get away from this, an equity on the part of the public where the Federal Government takes tax money and supports in this instance as I illustrated, provides the full financial investment necessary to bring about the invention. Now I think the public has some right in it.

This firm was paid to do a job. It did the job. It got paid for it. Now I agree with you that possibly it should have some preference in the arrangements made then for the further refinement and processing of the idea.

Mr. McKie. I agree with your statement, Senator, but let me point out that the public money is being spent not to develop the patent, but to develop the invention itself.

Senator McClellan. That is right.

Mr. McKie. Now if there is a need for the use of the patent to encourage the development, then it seems best that the patent ought to be in the person who made the development itself and not go to the Government and come back.

Senator McClellan. We come back to this point. Here is the Government that places one firm or one research institute or one private enterprise in a position to greatly profit at the expense of the taxpayers for a part of it that was developed primarily for the benefit of the public at the taxpayers' expense.

Mr. McKie. Well now, there must be a profit involved or else the product won't be produced, of course.

Senator McClellan. That is right, but that profit, should it go exclusively to one, or that opportunity for profit be made available to others in the same enterprise?

Mr. McKie. If it is, I think it should be available equally to all. That is if the Government owns the patent right, the right should be used in such fashion that everybody has a chance to use it.

Senator McClellan. Perhaps that would be true except for this. Again we come back to this. You are not sure it is going to work. You have got the patent. But you are not sure that it is going to work. Somebody has got to take the risk of an investment of $400,000 or $500,000 we will say, in order to determine that it will work, and after that expenditure, it may develop that it is not practical and not useful, and therefore all of the money invested has gone down the drain.

You say it ought to be equal, should the Government get the patent, and you say to everyone, "Here is the development, go ahead and develop it." Would anybody develop it?

Mr. McKie. In some cases yes, in other cases no, without exclusivity by reason of the patents.

Senator McClellan. Would the public interest suffer by reason of nobody doing it?

Mr. McKie. It is quite possible that it would; yes. In some cases, of course, certain products are on the market that shouldn't be there at all.

Senator McClellan. I come back to this. Anybody who says this whole thing is simple——

Mr. McKie. You are right, you are very right, Senator McClellan. But there was one other point.

Senator McClellan. I am not sure what is simple when you say this is simple.

Mr. McKie. There is one other point I would like to bring out. There are many inventions that are made under support of Government money which are not the objects of the contracts themselves. They are incidental to the contract. They may be due primarily to the background of the contractor, for instance, whether or not it is in the public health and safety field. Those inventions I think should be treated differently than others, and I am speaking only for myself in this area.

Senator McClellan. I think there are areas where that is true, and that is why it is so difficult to write a statute here that would give equity.

Mr. McKie. I think you can make a distinction in respect of the object of the invention. If you take your illustration, in which the Government is granting a great deal of money to someone to come up with a cure for a disease, now that invention of the drug that cures that disease might be in one category. However, all inventions made incidental to that contract, such as a new process for synthesizing a a new drug or a new component that must be used to arrive at that drug, I think that could well be in an entirely different category.

Senator McClellan. Very well, go ahead. I did not mean to interrupt you too much.

Mr. McKie. Let me point out further that with respect to the possible——

Senator Burdick. Mr. Chairman.

Senator McClellan. Senator Burdick.

Senator Burdick. Before we leave this field of inquiry, I would like to ask a question. My question would be very similar to the chairman's, to be perfectly frank. But I want to add another facet to this argument.

If we were to follow your suggestion, and give patent rights to an individual firm where all money has been expended by the Federal Government in making a discovery, what would happen if that firm sat on its patent and did nothing? What recourse would the Government have, or any other individual have, to process it? Suppose they did nothing, and that is not unusual, to do nothing.

Mr. McKie. Under S. 2326, the Dirksen bill, there would be a right to apply for compulsory license after a limited period of exclusivity. That is, nobody could suppress an invention within the provisions of this bill.

Senator Burdick. What is the period under that bill?

Mr. McKie. Three years; 3 years after the invention is made.

Senator Burdick. But they could sit on it for 3 years at least.

Mr. McKie. That is possible. It is very unlikely that such would occur.

Senator Burdick. If the Government had it and there wasn't any action, they could give a license to someone else.

Mr. McKie. That is right, but I think S. 1809 provides for the same period of exclusivity, if I am not mistaken.

Senator Burdick. That is all.

Mr. McKie. Thank you, Senator. I was about to refer to the profiteering aspects of this, and this is in the same area actually as you have just brought out.

Under S. 2326, it would be impossible for a contractor who had a patent right by reason of Government research and development money to profiteer to an unconscionable extent in this area, because of the compulsory licensing aspects of the bill. It would be possible then for a competitor to come in and ask for a license and if he could prove that he was capable of satisfying the need, then he could get a license within the provisions of S. 2326.

Senator McClellan. Anything further? Thank you very much.

Mr. McKie. Thank you very much, Senator.

Senator McClellan. Dr. Barr, will you come around, please? Will you identify yourself, please, sir? You have a prepared statement?

STATEMENT OF JOHN A. BARR, DEAN, SCHOOL OF BUSINESS, NORTHWESTERN UNIVERSITY, ILLINOIS

Mr. Barr. I have a prepared statement. I will read it, and I can do it well within the 15 minutes, Senator. I might say I am not a doctor.

Senator McClellan. I beg your pardon. I see you are a dean. I apologize. Some lawyers are doctors.

Mr. Barr. My name is John A. Barr. I live at 790 Sunset Road, Winnetka, Ill. I am dean of the School of Business at Northwestern University, Evanston, Ill.

I have held this position only since June 1 of this year. For approximately 30 years prior to June 1, I was associated with Montgomery Ward & Co., and was chairman of the board of directors of Montgomery Ward for the last 10 years of that period.

I was a trustee of Northwestern University for 18 years prior to June 1, and served as a member of the trustees' patent committee for 5 of those years. I was chairman of the patent committee for 4 years.

As chairman of the trustees' patent committee, which is responsible for the university's patent policy, I had occasion to consider various problems involving patent rights in relation to research at the university. I also had occasion, from time to time, to consider the

Government's patent policy, particularly as it related to work at the university.

In my present position as dean I have a direct interest in the resources available to support the research and teaching activities of the university, and I retain a direct interest in the patent field as a member of the patent committee of the faculty.

In my testimony today I will limit my remarks and observations to the experiences and interests of Northwestern University. I believe, however, that the interests, experiences, and concern of Northwestern in this field are fairly representative of the interests, experiences, and concern of many other institutions of higher learning.

The direct objectives of the university are effectively to teach the students who come to us, and to advance the frontiers of knowledge. The university is interested in research because research is important to the fulfillment of both these objectives. Research as a general rule, is the source of new knowledge, and research contributes to the vitality of the faculty and to the effectiveness and fullness of their teaching.

The Government also is interested in research because the development of new knowledge and the stimulation generated by research are important to the growth of the economy, to the public health and welfare, and to maintaining a competitive position with and hopefully a competitive advantage over, the nations on the other side of the curtain.

There appear to be many similarities between the interests of the Government and the interests of the university in the field of research and the related field of patent rights. The interests of both would be harmed by any curtailment of research activity; the interests of both are basically noncommercial; and the facilities and resources of neither should be dedicated to advancing the private interests or competitive position of any particular entrepreneur.

Because of this, I thought it might be of interest and helpful to you in your deliberations of how best to protect and advance the public interest, so far as the patent policy of the Government is concerned, if I told you something about our experiences with patent policy and patent rights at the university.

To satisfy its need for research activity the university relies on research grants from both the Government and from private industry. This necessarily raises the question of how patent rights should be treated as between the university on the one hand and the grantor of funds on the other.

Our patent policy at Northwestern for many years provided that the title to any patent of discoveries resulting from research performed at the university must rest with the university and that exclusive licenses would not be granted to any sponsor. There was in no way for any commercial firm to secure patent or exclusive rights arising from research at the university, regardless of the nature or extent of their sponsorship. The university was motivated by a desire to avoid any possibilty of its facilities or resources being used to advance the competitive interests of any individual company.

Two cases which the faculty presented to the trustees' patent committee last year illustrate the type of problem which arose under this policy and which led to a liberalization of the policy.

In the first case, company A asked a faculty member to undertake a research project in the field of engineering. The company offered to pay the full cost of the project in return for any patent rights which might arise from the research involved. The university rejected the offer because of the policy provision that all patent rights arising from research at the university must accrue to the university. The university offered only to grant a nonexclusive license to the sponsor to use any discovery which might result from the research. The company stood pat on its original offer. Understandably, it did not feel justified in investing several thousand dollars in the project if any resulting discovery would be equally available to its competitors.

The faculty was unhappy with this result because they felt the proposed project to be worthy basic research which might produce new knowledge and which, in any event, would be of scholarly value to the faculty members and graduate students involved.

The second case arose in the chemistry department where basic research results in the development of dozens of new chemical compounds each year. These compounds are synthesized in the course of basic research studies with no thought of possible commercial exploitation. The university does not know, and has no facilities or resources for ascertaining, whether any of these compounds have practical value. Some of these compounds might have great value, such as a drug to be used in the treatment of disease, or as a pesticide or fungicide or weed killer for use in agriculture. There is no way to determine whether any of these compounds are of practical value except by extensive testing at substantial cost.

In this setting, company B approached the university and offered to test a number of these new compounds to determine whether they were of practical value. Company B was prepared to spend a substantial sum of money for this purpose if the university, in turn, would grant to it an exclusive license to produce any of the compounds found to have commercial value. The university was forced to reject the offer because of its policy against granting exclusive rights to any one company. The practical result of this position was prevention of any determination of whether any of the compounds would be useful or beneficial to society, and precluded any commercial development which would have made any such benefits available to society. While the university's position was, in itself, quite proper from the standpoint of intellectual independence and freedom from commercial exploitation, the result was not in the public interest. No one could say that one of these new compounds sitting on the shelf was not a valuable lifesaving drug.

As a result of these and similar experiences, the university's trustees amended the university's patent policy last year to permit the granting of exclusive licenses or the assignment of patent rights to commercial sponsors of research, and to others, in specific cases approved by the patent committee.

I relate these university experiences to you because I believe they are relevant to your consideration of what the Government's patent policy should be.

Consider, for a moment, the last case which I related. Suppose that the research which resulted in the development of these new

chemical compounds had been partially financed by a Government research grant, and suppose the Government's policy was to require that all patent rights arising from research involving use of any Government funds must be vested in the Government. Would not the practical result be the same as it was under the university's old restrictive policy? The compounds would gather dust on the shelf, and the public would never have an opportunity to enjoy the benefits they might hold. The university does not have the facilities or resources to test the compounds to determine their value to society. And the commercial companies who do have the facilities and competence to test, develop, and market the compounds would, as a practical matter, be precluded from doing the job by a Government policy which denied them rights of exclusivity which are properly necessary to justify their risk of investing funds in testing compounds of unknown value.

I believe that this experience with company B, which is representative of other similar experiences, demonstrates the fact that in any determination of Government patent policy, provision must be made for granting adequate privileges of exclusivity to a commercial firm which assumes the risk of testing and developing discoveries of unknown value, even though the research which produced the discoveries was partially financed by the use of Government funds. Otherwise, many such discoveries would never be tested and their benefits never be made available to the public.

Senator McCLELLAN. May I interrupt to inquire if this policy would apply in fields other than drugs or chemicals?

Mr. BARR. I think it would apply in any field.

Senator McCLELLAN. In any field?

Mr. BARR. In any field.

Senator McCLELLAN. The same principle?

Mr. BARR. Yes.

Senator McCLELLAN. In other words, you might very well deprive the public of the use of many instruments of great value and convenience if the Federal Government just simply took the patent and said it is available to anybody?

Mr. BARR. Anything which is worthy of patent is of some benefit to society, to the public. Otherwise it wouldn't be worth patenting. This is true of medicine and that is true in other fields too.

Senator McCLELLAN. But what you have been saying here, in its raw state the patent may not be any good until it is proven.

Mr. BARR. It may not be.

Senator McCLELLAN. And the cost of proving is what would keep it on the shelf.

Mr. BARR. That is right.

Senator McCLELLAN. If everybody had an equal access to it.

Mr. BARR. That is right.

Senator McCLELLAN. If nobody is going to get any benefit from making the risk investment, if there is no prospect of them getting any advantage or any return on that investment, they wouldn't make it.

Mr. BARR. I think that would be true in the field of electronics, engineering, or medicine. I don't see any distinction.

Senator McCLELLAN. You don't see any distinction?

Mr. BARR. No, sir.

Senator McCLELLAN. That is why I wanted to emphasize it at this point. All right, proceed.

Mr. BARR. The first case which I related, the instance where company A refused to award a research grant to the university unless its investment was protected by a grant of exclusive rights to any discovery which might result—also illustrates a point which is relevant to the Government's policy.

As I mentioned before, the university is dependent on both public funds and private funds to finance its research activity. Frequently, funds from both sources become involved in different phases of a research study. If the Government were to adopt a restrictive policy requiring that all patent rights arising from research involving any Government funds must vest in the Government, the result could well be a refusal by private companies to support any research project which might be related to or to some extent dependent on another research study involving Government funds. Just as company A refused to support the project in the actual experience which I related, where, for another reason, the company was denied exclusive rights. The harm of this would be the availability of less private funds to finance research at our universities, and, consequently, a curtailment of research activity.

Senator McCLELLAN. May I ask you if you think what you have just related here, that private industry wouldn't join in and make a contribution to a joint project, so to speak, do you think that is a reasonable assumption?

Mr. BARR. I think it is.

Senator McCLELLAN. That they wouldn't do it?

Mr. BARR. I think the incentive for private industry to invest risk capital in research activity rests on the strength of the profit motive, and so far as research and development areas are concerned, it is the protection of exclusivity which flows from our system of patents which holds forth that opportunity to make a profit.

Senator McCLELLAN. Do you think such a policy then would simply dry up a great deal of the source of private research capital?

Mr. BARR. I think its tendency would be to dry up the source of private research funds, and that is the reason we are concerned with it.

Senator McCLELLAN. That certainly wouldn't be in the public interest.

Mr. BARR. It would not.

Senator McCLELLAN. Very well.

Mr. BARR. Based upon my experiences as a businessman and as a university trustee and officer, and based also upon my interest in furthering the cause and quality of higher education and in strengthening the American system of free enterprise, both of which I believe to be in the public interest, I respectfully submit that these principles should be recognized and implemented by the committee in its determination of the Government's patent policy:

1. The great progress which has been achieved in America in science and technology and medicine is largely due to the enterprise and activity of private entrepreneurs, motivated by a desire and an opportunity to make a profit. Patent protection has been an important factor in attracting risk capital to research and to

the discovery, development, and marketing of new products. Any patent policy adopted by the Government should recognize the constructive force of the profit motive in our society. The Government should avoid any policy provision which would weaken or curtail the force of this motive.

2. The public interest requires that the benefits of useful discoveries be made available to society, and no policy should be adopted which would operate to deny or curtail the availability of such benefits. The testing of new discoveries for usefulness and value, and the development and marketing of useful discoveries is a commercial process. Even though Government funds have contributed to a discovery, provision must be made which will permit private entrepreneurs to test discoveries of unknown value with a right to develop and market those which prove to be useful with a commensurate degree of exclusivity.

3. Research is important both to our institutions of higher learning and to the public. Any policy which would have the effect of curtailing research, either research supported by public funds or research supported by private funds, would be harmful to our universities and contrary to the public interest. In cases where both Government and private funds have contributed to a research study which produces a useful discovery, provision must be made which will give the private sponsor an opportunity to develop and market the discovery on a basis which recognizes his investment of risk capital in the project, and affords him a commensurate degree of market exclusivity.

4. As a general rule, in those instances where Government research funds are granted to a properly recognized or accredited university or college, any patent rights arising from such research should be vested in the grantee university or college, to be administered in accordance with a Government approved patent policy of the grantee institution. The university, like the Government, is dedicated to the public interest and is not engaged in commercial manufacturing or marketing. The vesting of proprietary rights to any such discoveries in the university would strengthen the motivation of university personnel to use the Government funds most effectively and efficiently, and would broaden the opportunity for scholarly contact and interchange between the scholars and scientists of the university and their counterparts in the commercial organizations with whom the university would work in securing the necessary testing, development, and marketing of useful discoveries.

All in all, my suggestions I am aimed toward a policy which will maximize the amount of research done in America, regardless of whether it is financed with public or private funds, which will strengthen the position of institutions of higher learning to make fuller use of their vast resources of scholars to advance the frontiers of knowledge, and which will give the greatest assurance that the benefits of new discoveries will flow through to the public through recognition and support of the strong constructive force of the profit motive in private enterprise. Thank you.

Senator McClellan. Thank you very much, Dean Barr. I know others may disagree with what you have presented, but certainly you have presented a very able statement here.

Mr. Barr. Thank you, sir.

Senator McCLELLAN. That deserves the closest attention and consideration of this committee.

Mr. BARR. Thank you, sir.

Senator McCLELLAN. And of our Government, in trying to arrive at a patent policy in the public interest. Thank you very much.

Dr. Suter and Dr. Maurice Seevers, if you would both come around, please, I think maybe we can hear both of you before we recess, and that will conclude the witnesses we have scheduled for today. Is Dr. Seevers here?

All right, then we will proceed with you, Dr. Suter.

STATEMENT OF DR. C. M. SUTER, DIRECTOR, STERLING-WINTHROP RESEARCH INSTITUTE

Dr. SUTER. Mr. Chairman and members of the committee, this statement will be very brief.

Senator McCLELLAN. Very well, you may read it.

Dr. SUTER. I am pleased at the opportunity to appear here today to comment on issues raised by S. 1809, the chairman's bill on Government patent policy. I am speaking on behalf of Sterling-Winthrop Research Institute, the pharmaceutical research division of Sterling Drug, Inc., a diversified drug company with over 40,000 stockholders and 13,000 employees here and abroad.

My name is Chester M. Suter. My graduate scientific education was in organic chemistry with an M.S. and Ph. D. from the University of Kansas followed by a postdoctorate fellowship at Yale University. Following this I was on the faculty of Northwestern University, Evanston, Ill., for 14 years, where my time was divided about equally between teaching of premedical and advanced chemistry students and doing research mostly in areas of medicinal interest.

When I left Northwestern I was chairman of the department of chemistry. I resigned to go to Winthrop in Rensselaer, N.Y., to organize a drug research facility on behalf of Winthrop and for Sterling Drug as a whole. Starting from scratch we now have a total staff, scientists and supporting personnel, of about 600. My publication and editorial experience includes numerous research papers, patents, and books. In recent years my work has been as much administrative as scientific. More information on qualifications would probably bore you, but are available in "American Men of Science."

As a director of medicinal research I am concerned about section 4, subsection (a)2, page 4, of S. 1809. This subsection has already been put into effect by NIH in its grants to universities and other nonprofit research groups. This policy has largely blocked collaboration between scientists of these groups and the pharmacologists in industrial laboratories. These biologists could determine whether the compounds made under NIH grants have the potential for practical value. The industrial people cannot logically invest in this effort because all results which might lead to a useful product are subject to confiscation by the NIH without recompense.

I might add at this point that we are continually deluged with other important problems, so it isn't a question of doing a project here or

not doing anything at all. But it is a question of doing something else which may appear to be almost equally important.

Senator McCLELLAN. Tell me how this policy now is detrimental to the public interest, the policy now in effect which you said I believe S. 1809 involves.

Dr. SUTER. As will appear later on here——

Senator McCLELLAN. All right.

Dr. SUTER. All right, I will go ahead, Sentor.

It is not always realized that the cost of biological testing and development of a new product is much more expensive than the original invention. An actual experience may emphasize this. This happened to come across my desk just at the time I was getting ready to come down here. Recently we obtained an exclusive license to an invention for a new product which may represent an advance in a certain area. The preliminary work on the invention by the outside party represented only a modest monetary expense. I think it would be very comparable to a grant such as NIH might give to a university. For us to get a suitable formulation ready for its first clinical study has cost us $281,000 during a 3-year period. Our expenses furthermore has just begun because at this point we would turn the product over to Dr. Moyer, for example, in accord with his earlier statement, for his work in clinical pharmacology. This represents the expense up to that point, because ahead of us are extensive clinical studies and further more detailed animal studies prior to submission of a new drug application. Without an exclusive right to market the product we could not afford to be interested in it. A similar invention, therefore, made under an NIH grant would go undeveloped. This, I urge, is not good national policy. The taxpayers may not get full benefit from $1 billion spent in grants in research aid under these circumstances.

When the NIH policy first went into effect I received a long letter from a university scientist asking about our testing NIH grant compounds. I had to turn him down as I could not run the risk of losing stockholders' money when other attractive work was at hand. In effect the NIH was trying to take over $100 worth of results after spending $10 or less. No private firm can take part in such a program, so testing of NIH-financed compounds has largely stopped. Contamination of a research program with a minor amount of Government money crowds the title to the rights on new products under present circumstances.

Senator McCLELLAN. You make a statement here which I would like to emphasize:

> No private firm can take part in such a program, so testing of NIH-financed compounds has largely stopped.

Dr. SUTER. That is certainly true in our place.

Senator McCLELLAN. You are talking about——

Dr. SUTER. That is our reaction to it, and I think it is never 100 percent true because there are always unusual circumstances, but I do have the——

Senator McCLELLAN. You say since the incentive has been cut off your institution is not interested?

Dr. SUTER. For the pharmaceutical industry as a whole, the R. & D. tab of $310 million, 96 percent is company money now, so that this indicates to me a break between the collaboration that might occur, you see, between the NIH and the pharmaceutical industry.

Senator MCCLELLAN. All right.

Dr. SUTER. I might elaborate on that point. This does not mean that we never take small NIH grants. There are occasionally projects which are not likely to lead to inventions, which are done purely on a package basis, and now and then as a matter of accommodation, so to speak, we have taken small grants in that area, although we do not have one at the present time.

This situation can be remedied by suitable modification of section 4, subsection (a) 2, so that medicinal inventions are accorded the same treatment as other inventions now receive and would receive under the proposed S. 1809. Until this is done an industrial research laboratory will rarely be interested in becoming involved in a Government-subsidized program where inventions are likely to occur. This applies to participating in the programs of others at company expense or seeking direct grants from Government agencies. I would regret seeing the present NIH policy continued and extended as a permanent program. A good analysis of the problem and a suggested alternative solution has been developed by the American Patent Law Association. This is published in the June 1965 bulletin of this association, pages 327-333, and, I believe, has already been given by W. Brown Morton as testimony before this subcommittee. He was scheduled, I know, on July 7. A more concise statement of the changes in S. 1809 that seem to us to be desirable are given in appendix A of the testimony by Dr. Austin Smith before this subcommittee on June 1, 1965, on behalf of the PMA. The point of view expressed by the American Council of Education in their excellent statement of July 20, 1965, is reasonable and covers a section of the area under discussion.

And I might add that I am very much pleased, and enthused, by the statement made this morning by Dean Barr, who gave his testimony just before I came up here. It is just a coincidence that we both happen to be from Northwestern. I have never seen him before. But we feel that his approach to this situation, whereby the university as a nonprofit institution acts on behalf of the public, is a very good approach to the matter of handling Government grants.

It might be pointed out that the Federal Government and the people of this country both share under any circumstances in any success that a company may have in developing a new medicinal product, spending some scientific work in a university. Physicians have at their disposal a superior new product prescribed for their patient, and the Government gets about half of the profits, if any.

If royalties on any such invention could go to universities, medical schools, or other nonprofit institutions, to strengthen their facilities, this would be a suitable and desirable consequence of the original grant I think from the Government to the university. That concludes my statement.

Senator MCCLELLAN. Thank you very much. The letters to which you refer are attached?

Dr. SUTER. Yes.

Senator MCCLELLAN. They will be published in the record at the conclusion of your statement.

(The letters referred to follow:)

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., August 9, 1962.

Dr. C. M. SUTER,
Director, Sterling-Winthrop Research Institutes,
Rensselaer, N.Y.

DEAR DR. SUTER: I am writing this letter to you at the suggestion of Prof. W. S. Johnson, chairman of our chemistry department. Recently we submitted to the National Institutes of Health a research proposal entitled "Amino Sugars of Potential Pharmacological Utility." The main portion of this proposal involved specific reactions in the aminosugar series, with emphasis on neighboring group participation, direct replacement reactions and reactions of aminosugar derivatives with organometallic compounds. In view of the pharmacological importance of the aminosugars, we also suggested that the substances prepared in connection with the above studies might be subjected to screening tests for pharmacological activity at any one of several companies who perform such tests. Since such compounds are indeed apt to have pharmacological characteristics of interest, it seems quite to the point to mention this possibility in connection with our proposed studies.

In the past, both the Abbott Laboratories and Merck, Sharp & Dohme have conducted routine screening tests in connection with compounds which we have prepared in some of our studies. Accordingly, we approached these companies before seeking collaboration elsewhere. In view of the agreements required by the NIH, however both of these companies regretfully expressed a lack of interest in screening the compounds to be produced from our researches in this area.

Accordingly, at the suggestion of Professor Johnson, I am writing to you to ask if your laboratories would be interested in collaboration with regard to routine screening of compounds in this class. In order that you know the requirements which the NIH would impose upon such collaboration, I am including herewith a copy of the NIH patent agreement recently forwarded to me by Dr. Helen Jeffrey, of the NIH.

I would be most interested to hear from you at your early convenience regarding the possibilities of conducting such screening tests in your laboratories, and in particular, as to whether the details of the patent agreement, etc., required by the NIH are agreeable to your company in connection with the conducting of such tests.

Hoping to hear from you at your early convenience in regard to the above matters, I am

Yours very sincerely,

WILLIAM A. BONNER,
Professor of Chemistry.

STERLING-WINTHROP RESEARCH INSTITUTE,
Rensselaer, N.Y., August 31, 1965.

Prof. WILLIAM A. BONNER,
Department of Chemistry,
Stanford University.

DEAR DR. BONNER: Your recent letter regarding the possibility of our testing certain amino sugars for pharmacological action has now been considered by several of us here. Although we recognize that there might be some interest in screening these compounds in several tests we think this is outweighed by the complications which would arise if a useful action were found.

We are already involved with so many complicated Government regulations and restrictions that we are unwilling to take on a project of this sort.

I am personally sorry to react in this way, but we feel there is not much alternative under the circumstances.

Sincerely yours,

C. M. SUTER, *Director.*

Dr. SUTER. As you may gather, I called the professor at Stanford regarding this letter, and he said he would be glad to have this included and attached to my statement.

Senator MCCLELLAN. Very well. I regret that the other witness is not here. He had a right to anticipate that he wouldn't be called until this afternoon.

Dr. SUTER. Thank you, Senator

Senator MCCLELLAN. Thank you very much. The testimony this morning has been very helpful I think. From it the committee will get some better understanding maybe than it has had heretofore of what can happen if we legislate a bad policy of Government in this field.

Certainly, if the Government makes an investment that results in an invention, that invention is taken by the Government to patent, and it is just put on the shelf and it is never developed, no one benefits from it, and the indications here are that in some instances inventions that could prove very beneficial to the public might never be developed and put on the market.

So this subcommittee has a very difficult task of trying to unravel this problem and get some legislation that will be in the national interest.

I regret the other witness is not here, but he had a right to expect to testify this afternoon. Since we will not be able to hold hearings this afternoon, we will try to hear Dr. Seevers Thursday morning. Tomorrow the subcommittee will hold hearings on copyright legislation. We had it scheduled that way. And Thursday morning at 9:30 the committee will resume hearings on the patent bills.

Senator Morse is scheduled to testify on Thursday morning, at 9:30 and immediately after that we will try to hear Dr. Seevers. We are beginning early Thursday morning so as to accommodate Senator Morse.

The committee will stand in recess until Thursday morning on the patent hearings, and until tomorrow morning at 10 o'clock for copyright hearings.

(Whereupon, at 12:35 o'clock p.m., the subcommittee recessed, to reconvene at 9:30 o'clock a.m., Thursday, August 19, 1965.)

GOVERNMENT PATENT POLICY

THURSDAY, AUGUST 19, 1965

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
TRADEMARKS, AND COPYRIGHTS OF THE
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 3302, New Senate Office Building, Senator John L. McClellan (chairman of the subcommittee) presiding.

Present: Senators McClellan and Burdick.

Also present: Thomas C. Brennan, chief counsel; Edd N. Williams, Jr., assistant counsel: Stephen Haaser, chief clerk, Subcommittee on Patents, Trademarks, and Copyrights; Horace L. Flurry, representing Senator Hart; and Clyde M. DuPont, representing Senator Fong.

Senator MCCLELLAN. The committee will come to order.

Our first witness today is Senator Morse, of Oregon. Senator Morse has introduced S. 2160 to amend the patent provisions of the Space Act of 1958. Since Senator Morse's bill relates only to the patent policies of NASA, it was referred to the Committee on Aeronautics and Space Sciences.

I shall direct that the text of this bill be printed in the record immediately following Senator Morse's testimony.

Very well, Senator. We are very glad to welcome you here this morning.

STATEMENT OF HON. WAYNE MORSE, A U.S. SENATOR FROM THE STATE OF OREGON; ACCOMPANIED BY HERBERT L. SPIRA, COUNSEL, SENATE SMALL BUSINESS COMMITTEE

Senator MORSE. Mr. Chairman, I appreciate your hearing my testimony this morning. I ask two things: first, that there be inserted in the record the full statement of some length that I have prepared. I will not take the time to read that.

I would also like to have inserted in the record a summary of that statement, from which I shall make my testimony this morning.

Senator MCCLELLAN. Is this what you want inserted in the record [indicating]?

Senator MORSE. Yes. That is the full statement.

Senator MCCLELLAN. The full statement, then, may be printed in the record at this point.

Senator MORSE. Then I would like to have my summary statement inserted in the record, preceding it, I think, Mr. Chairman, because I am not going to be able to read all of that, and I would like to have it included in the record in its entirety.

Senator MCCLELLAN. All right, the summary statement presented by the witness will be inserted immediately preceding the full statement which I have just ordered be inserted in the record.

(The summary statement and the full statement referred to follow:)

SUMMARY OF PATENT STATEMENT

Since 1947, the American taxpayer has spent $85 billion on Government-financed research and development. In the next 6 or 7 years $85 billion more will be contributed by the taxpayer and appropriated by the Congress for these purposes. The commitment of public funds on this scale to scientific research and development is surely one of the most significant economic events of modern history.

This subcommittee has the task of formulating national policies for disposition of the rights to the commercial exploitation of patent property created as a result of these public expenditures.

The chairman's letter of invitation to Members of the Senate is one more indication of thorough and conscientious approach which the subcommittee has taken to this extraordinary and complex task. I feel that the Nation is fortunate in having such consideration by the chairman and the diligent participation by the members of the subcommittee which is being brought to bear on these problems.

My formal statement is rather lengthy, since there is a good deal of statistical and historical material which I would like to have available to the subcommittee. I would like to proceed with about a 20-minute summary of the highlights of the statement. If there is time remaining, I would be glad to go into particular areas which the subcommittee believes might be helpful.

I am aware that the subcommittee is very much concerned with the commercial utilization and exploitation phase and I will place my emphasis there.

In accordance with the chairman's wishes, I have included in my statement an outline of my activities in the patent and public property areas, including the history of the Morse formula, my participation in the atomic energy legislation, and the legislation which I have introduced on NASA patent policy during the 88th and 89th Congresses. My position, as embodied in S. 2160 on NASA patent policy, is that taking of title by the Government in behalf of all of the people should be coupled with a flexible system of licensing, such as was discussed with Dr. Shannon on Tuesday morning (August 17). Under procedures which I envision, this system will provide equal protection and even greater incentives than waiver of patent rights for contractors developing and marketing inventions.

A precondition for such a flexible policy is, of course, the assertion of title by the Government agency concerned in the first instance. Once patent rights are waived to an individual contractor for 17 years, flexibility is lost forever.

At the opening session of the hearings, the President's Science Adviser gave great emphasis to this issue of utilization. My experience makes me sensitive to additional considerations of great importance. An excellent summary of these factors is found in the findings and conclusions of the Attorney General's Report of 1947, which I would like to take a moment to read:

IV. INVENTIONS MADE BY GOVERNMENT CONTRACTORS

"1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of

the national economy; and will thus strengthen our American system of free enterprise."

This work entitled the "Investigation of Government Patent Practices and Policies," was begun at the request of President Franklin D. Roosevelt in 1943 and during its course, 14 Federal agencies and 10 national governments were consulted. It was ultimately published in 1947, and has formed the foundation for a position in favor of the public interest, which the Justice Department has adhered to from that day to this. I invite the subcommittee's attention to this document, as it is the most comprehensive and pursuasive study I have been able to find.

I believe that these considerations, together with the evidence gathered by Secretary of Agriculture Benson (cited at p. 7 of my statement) that Government title does not impede the commercial development of inventions, are convincing of the value of a basic title policy for Government-financed R. & D.

However, the subcommittee is quite correct in coupling its consideration of ownership provisions with the system of utilization. The two go hand in hand.

It is my feeling that contractors should feel that they are receiving completely fair treatment from the Government in this area, just as small businessmen, taxpayers, and individual inventors should feel that their interests are getting an even break.

In contrast to the bright successes of title policy, in the areas of agriculture, TVA, and atomic energy, let us examine the consequences of the license policy, as exemplified by the Department of Defense, and more recently of NASA. I have spent a considerable time analyzing the effects of our Government contract and patent policies on increasing concentration of wealth and assets among the Nation's largest companies. At this time, I am pleased to make these findings available to the subcommittee.

As the subcommittee is aware, the Council of Economic Advisers told the President in January that:

"* * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole. * * *

I am informed that mergers hit an alltime high of 991 in the first 6 months of 1965.

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 percent of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

To illustrate the seriousness of the concentration issue, particularly in the Department of Defense, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

"The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D.).

"* * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture each concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials?" ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that, in fiscal year 1962, 97 percent of DOD research awards were made on a nonprice, noncompetitive basis (hearings, "Testimony of Dr. R. J. Barber, Southern Methodist University Law School," p. 52).

It should be further noted that for the same year, 10 firms received 56 percent of DOD's total research money; and for NASA, the top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists (hearings, loc. cit. Mar. 7, 1963, pp. 56–57).

Now, in the face of these tendencies, which (as I document in an appendix to my statement) the Justice Department has viewed with alarm under both Democratic and Republican administrations since 1947, what has been the impact of Federal research and development policy?

A most trenchant analysis of the dangers in these trends was made by a Republican Attorney General, Herbert Brownell. In 1956, he declared, in the following language, his concern: "with the future of competitive enterprise, and it is important that its share of this (research) activity be administered to promote competition. * * *. [W]hat indications that are available warn that the Government expenditures may not run counter to the industrial trend toward concentration, but in some degree may actually enforce it. * * * The disproportionate share of total industrial research and development in the largest firms may foreshadow a greater concentration of economic power in the future. * * * (A) present concentration of such manpower and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants."

These trends are relevant to the question of who should receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum, Federal R. & D. policy in the administration of contracts, as well as in the allocation of patent rights, should attempt to counteract trends toward monopoly and concentration, rather than reinforce them as these policies, as they have been doing.

To return to the issue of utilization; my position has been private enterprise, as in S. 2160, should be given the sole task of developing and commercializing inventions arising out of Government-financed research.

However, there must certainly be appropriate safeguards for the economy, the taxpayer, the small businessman, and the consumer in the form of the terms and conditions on which this development is carried out. These terms and conditions now engage our attention.

Seventeen years is a long time in this era of breathtaking technological change. One company, General Electric, is fond of saying in its annual report that half of its sales are attributable to products which did not exist 10 years ago. A system where the Government takes title and provides for a liberal granting of exclusive and nonexclusive licenses, would allow a more realistic period of 3 to 5 years for a company to proceed with development and marketing phases with absolute incentives and absolute protection. At the end of such a period, the company could come back into the agency and make a showing of what it had done, as a basis for a possible renewal of this license for a renewal period.

Not only would this give a complete flexibility as to the number of years involved, but as to other terms and conditions of the grant. For instance, there could be consideration of States and municipalities which must provide services for all of the people, and of hospitals and universities, which are rendering services in the public interest. Such a system could provide for equitable access for small businesses which did not participate in the original contract for research or development. They could also provide for a determination of royalties, in certain cases, which would provide a return to the taxpayer of some of his $15 billion annual investment. An additional feature should be that the so-called "walking-in provisions" should require walking-in by the contractor, who desires to retain a preferred position. This would save the Government the administrative burdens and expense of monitoring and enforcement. A renewal proceeding would also provide an opportunity for other parties to present their views and claims on the basis of changing circumstances.

I now turn to the field of procedure. As the chairman knows from his long career in public life, the procedural section of any bill is just as important as the policy declaration, if not more so. My formal statement contains several recommendations as to procedural devices, and I would like to point up a few of these.

I have been especially concerned with the status of small business under patent legislation that may be enacted. May I say that my small business philosophy is not the protective variety. I believe that we must give small business of today an even break so that they can grow up to be the large substantial businesses of tomorrow. This keeps our economy dynamic. It is particularly important in new fields which are being opened up by Government-financed research and development. Firms like IBM, Texas Instruments, or Tektronix, from my own State of Oregon which will be testifying before you today, were all once small businesses.

The problem is how to provide access to the $15 billion products of Government R. & D., which is performed by relatively few firms, for all of the small business community. The subcommittee has a golden opportunity to do this.

I say particularly to my brother member of the Small Business Committee (Senator Scott) that Congress should take the time and trouble to devise the procedural features which will carry out this access. This would not be a Republican measure or a Democratic measure but a bipartisan effort to strengthen the foundations of our economy by giving the small man a fair shake. In S. 2160, my bill on NASA patent policy, which I have attached as an appendix to my statement, several of these procedures are set forth. I would like to advance them for the committee's considerations. Since there are few landmarks in this area, I would like to stress that these suggestions should not be regarded as definitive. These are efforts which I hope might contribute to the creation of a workable system.

These procedures have three features: Notice, hearing, and limited judicial review.

I am also concerned as is the subcommittee, with the interests of the taxpayer. The taxpayer would benefit, under the licensing system described above, from increased competitiveness and lower prices of the finished product. He could also benefit immeasurably from the institution of a general policy of sale or royalty of the patent rights in areas where this is a practicability. I have recommended in my statement that the committee secure the opinion of a fiscal expert on the amounts that might be realized through such a royalty system.

The cause of the individual inventor has also been mentioned. I believe that consideration of this legislation presents an outstanding opportunity to give greater standing and possible financial reward to the individual inventor. Any provision governing the relationship between the Government and the contractor on this point should probably be conditioned upon the relationship between the contractor and the individual employee.

To conclude, I shall attempt to sum up the directions I believe the committee should take. With respect to S. 789, I believe it is a fine example of a procedural trap. As stated by the Department of Health, Education, and Welfare, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long, arduous, and exceedingly difficult, and in many cases, impossible task."

S. 1809 is, of course, the principal bill before the committee. I commented upon the provisions of this bill in considerable detail in my formal statement. I might repeat that I consider section 11, which repeals the public interest patent provisions of the last 30 years, to be unsound and undesirable. This legislation, rather than reject the past, should be built on its monumental successes.

With respect to the chief section, section 4, I believe the policy of favoring the waiver of patent rights to the contractor doing the work is undesirable for the reasons that I have discussed above. This policy goes even further than the 1963 patent statement in following the practices of the Defense Department which are getting the economy in so much trouble. The fine provision placing the presumption title in the public interest is applicable only to the area of health, welfare, and the public safety. The wisdom of this policy is demonstrated by the case of the test for PKU which has come in for a good deal of discussion on the Senate floor, in the committee, and in the press.

On August 12, 1965, two Senators introduced a bill (S. 2402) that would appropriate "such sums as may be necessary" to buy a test for every newborn baby in the country. A little arithmetic demonstrates that the sums necessary would be more than $2 million higher under a license policy than under a title policy. Since the original appropriations for developing the PKU test are estimated to be about $1 million, it can be seen that a failure to take title would result in the taxpayers being charged annually $2.5 million for something they had already bought for $1 million. This matter is detailed in an appendix to my statement.

However, if it makes sense to safeguard the taxpayers' investment in this area, where the taxpayer puts up an estimated 15 to 25 percent of the research money, does it not make even more sense in scientific instruments, where the taxpayer furnishes 57 percent; or electronics and communications equipment, where the taxpayers' share is 67 percent; or aircraft, where the share is 89 percent? (Federal Bar News, November 1963, p. 357.)

In the final appendix of my statement, I set forth data confirming the fact, which was discussed on Tuesday morning, that as we move toward fields where the Government needs "end items," the proportion of development paid for by the

Government approaches 100 percent. For instance, there is almost complete transference between items such as the KC–135 jet tanker and the Boeing 707; and the military synchronous satellite and the Early Bird commercial satellite. It is thus in the defense and space areas where the necessity of protecting the public interest by this type of policy is the greatest.

My statement also goes into detail on the reasons that S. 1809 does not give an even break to the small businessman, the taxpayer, the farmer, or the consumer. I also present evidence as to the undesirability of procedural standards such as "exceptional circumstances" and "special circumstances" which are important in S. 1809. Lastly, S. 1809 would seem to make no improvement in the unfortunate situation at the space agency, where congressional intention and policy is constantly being violated under the present NASA regulations. It is my impression that the bill will merely repeal the congressional mandate and leave matters to the same administrative discretion which has created this unfortunate situation.

Some suggestions are also advanced as to data which the committee should obtain and update relating to matters which have been the subject of subjective opinions but which no firm data has been advanced.

It is my belief that any patent legislation should be governed by the following six general principles:

(1) A clear policy statement that Federal research and development property is a "natural resource belonging to the people of the United States," and must, therefore, be safeguarded accordingly.

(2) Plain and certain penalties for the giveaway or unauthorized disposition of Federal R. & D. property.

(3) Provision for preserving the many congressional patent protections that have been ordered into law over the past three decades.

(4) Practical means for discouraging monopoly and concentration, and thus protecting the interests of small business and an "open economic system."

(5) Clear and unambiguous standards for separating private and public interests in the commercial development of the property.

(6) A system whereby Federal R. & D. property sought by private companies for commercial development could be sold or licensed to them for an amount equivalent to fair market value, and the same property sought by other public institutions for dedication to public purposes could be sold or licensed for half of the fair market value wherever practicable.

In S. 2160, I have suggested additional provisions for public licenses and royalties, and procedures which would result in written findings by the head of an agency as to both public versus private interests, and value of patent interests. These proposals might be helpful to the subcommittee in formulating the necessary standards, and I commend them to the subcommittee's consideration. If I can further assist the subcommittee during its deliberations, I would be glad to do so.

STATEMENT OF SENATOR WAYNE MORSE

Mr. Chairman, members of the subcommittee, I am most grateful for the subcommittee's courtesy in scheduling my appearance—for several reasons.

The patent bills presently before you raise what I consider to be the most important economic issues of this generation. They involve the economy of my State, the future welfare of the 90 percent of America's business population which is small business, and the public interest of the taxpayer in property which is accumulating at the rate of about $15 billion a year.

BACKGROUND

As the subcommittee is aware, I have been concerned with safeguarding the property in the public domain since I came to this body. The so-called Morse formula grew out of consideration by the Armed Services Committee, in 1947, of a policy for disposal of the mountains of surplus military property that was left over from World War II. We decided, rather than give this public property away, that it should be sold at fair market value to private companies, and for 50 percent of market value to States and municipalities for public use. Since then, I have sought to apply this formula to all transfers of real estate and tangible personal property coming before the Congress. If I may say so, the Library of Congress made a tabulation in 1962, indicating

that an area about two-thirds the size of Rhode Island had been made subject to this formula, and about $800 million had thus been saved and returned to the Treasury. I believe that the chairman is interested in such economy measures.

In addition, I have devoted myself to the preservation of the public's interest in their navigable streams and rivers, through multipurpose river valley development.

These concerns led me to take an active part in the debates on the atomic energy and space communications legislation of 1954 and 1962, where large amounts of intangible patent property and technology belonging to the U.S. taxpayer were at issue. They have also prompted me to introduce bills in the 88th and 89th Congresses to correct the continuing violations of congressional patent policy by the National Aeronautics and Space Administration. In addition, I have been able to participate in the consideration of the economic aspects of patent policies by the Select Committee on Small Business during the past 3 years.

As the chairman pointed out, on the first morning of the hearings, the issues are complicated, and it is difficult to gain an understanding of all of their facets.

It is a source of satisfaction that it is possible for me to participate in the "great debate" on patent policy. I shall try to assist the subcommittee by relating my experience and explaining my views on the bills before you and the broad questions which I feel they raise.

SIGNIFICANCE OF THE ISSUES

In my judgment, the sheer amount of public property the subcommittee is dealing with is enough to elevate the significance of a congressional decision to the level of those made in the Northwest ordinances, the homestead acts, and the land-grant college legislation. A little later, I shall show how all the public property disposed of under these great acts of Congress was worth less than $1 billion. Yet, we are talking here about property being paid for out of taxes at the rate of $15 billion a year.

Any congressional declaration of policy in this field will be looked upon as a watershed in the philosophy of this country. It will have far-ranging and unforeseen effects on the climate of opinion for decades to come. Senator Norris, in his autobiography, made the following statement:

"The early twenties brought the American people to their knees in worship at the shrine of private business and industry.

"It was said, and accepted without question by millions of Americans, that private enterprise could do no wrong.

"The next 12 years was to produce one of the great classic struggles of the legislative branch of the National Government, the battle of the Tennessee Valley Authority, better known as TVA." ("Fighting Liberal," by George W. Norris, ch. 2.)

After the breakthrough forged by Mr. Norris, and his colleagues in the legislative and executive branches during the 1930's, there was a good deal of forward-looking legislation in the interest of all of the people of this country, wherein patent rights were retained by the Government and made freely available to the public.

It seems to me, Mr. Chairman, that the exigencies of World War II and the cold war have made the wheel come full circle. We now hear considerable advocacy of the position that only the largest private corporations are fit custodians of property developed at public expense. I submit that we who have been in public life for some time, and have seen these cycles of publicity, and what passes for "public opinion," have a solemn obligation to protect the statute books of this country from the notion that private business can do no wrong.

There is, secondly, significance of a very material nature in the disposition of public property worth $15 billion a year. The way Congress distributes these valuable commercial rights will have a measureable impact on the structure of our economy, the balance between small, medium sized, and large businesses, the trends toward concentration and monoploy, and the relative power of the civilians and the military in controlling our Government.

Third, this legislation, by proposing to repeal the public interest patent sections of many benchmark acts of Congress threatens to undo the work which many of

us have fought for, and devoted our careers in Congress to, over the span of the last 30 years.

May I comment on these three points in reverse order.

EXISTING STATUTORY SAFEGUARDS OF THE PUBLIC INTEREST SHOULD BE PRESERVED

As you are aware, section 11 of S. 1809 would, under the label and in the guise of "technical amendments," sweep away patent provisions of 10 laws enacted by Congress since 1935. The patent sections in this legislation were not "technical matters" when they were considered by the various committees of this body and of the House of Representatives. They were not "technical matters" when they were debated on the floor of the Senate, in the press, and throughout the country. They were not "technical matters" when they were signed in the law of the land by our Chief Executive.

As was observed by the distinguished junior Senator from Alabama and the chairman of the Commitee on Small Business, Senator Sparkman, on the floor of the Senate on July 24, 1954:

"In other words, these private power and industrial companies want to determine who should be licensed to receive the benefits of discoveries and inventions financed primarily by the Federal Government and also what price they should pay to receive these benefits. This a tremendous amount of power which could be used to stifle competition by excluding small producers and distributors of electricity.

"In my mind this is the meat, the core, of the legislation which is now proposed to amend the 1946 Atomic Energy Act. * * * There are other issues, but we must not lose sight of the big show—the attempt of these industrial giants to obtain exclusive private patents." (Congressional Record, vol. 100, p. 11789.)

Mr. Chairman, patent rights to public property are still the "big show," and section 11 is an attempt by private business and its representatives to steal the show.

A little later in my testimony I will show how few companies—actually only about two or three dozen—stand to receive the lion's share of these public patent rights.

I have searched the Record for compelling reasons for undoing the 10 legislative provisions that section 11 proposes to extinguish. I have looked for studies; for empirical data. I have yet to find any reasons or data. The simple explanation, I suspect, is that they do not exist. On the contrary, the evidence I have found points uniformly toward the retention of these provisions on their merits.

TITLE POLICY HAS SHOWN ITS WORTH

Let us take a hard analytical look at the consequences of the "title" and "nontitle" patent policies, beginning with the oldest sections in point of time, those dealing with agriculture and forestry.

First, let me say to the subcommittee that I am familiar with the problems of a State in transition between an agricultural and industrial economy. The economy of the State of Oregon is quite similar to the economy of a State like Arkansas in many ways:

In its reliance on agriculture and forest products.

In the fostering of industrialization, based largely on byproducts and new developments in the technology of the agriculture and forestry fields.

In its recreation industry, stemming from location astride the Pacific flyway, as Arkansas lies along the Mississippi flyway.

The passages of the 1962 Industrial History of Arkansas regarding the State's efforts to plan for compatibility among these elements could just as well have been written about my State.

The patent policies of the Department of Agriculture, which were worked out laboriously over 80 years, and are embodied in the 1935 and 1938 acts, have a direct bearing on such economic activity. As is well known, this legislation carried forward the policy originally set forth upon the Department's establishment. In 1862, the Department was "required to acquire in diffuse of the people of the United States useful information on subjects connected with agriculture, in the most general and comprehensive sense of that word, and to further, to procure, promulgate and distribute among the people new and valuable seeds and plants." (Organic Act of 1862, 5 U.S.C. 411.)

The 1938 act established four regional utilization research laboratories, to search out new outlets and wider markets for farm products. In accordance with this philosophy, the patent policy of the Department of Agriculture has been to retain ownership in the Government, so that access can be given freely to any responsible person or business concern.

What have been the results of this policy? As President Johnson stated in his farm message in February:

"Thirty years ago, over 7 million American families lived on the farm. Today 3½ million families feed a population that has grown by 50 percent. Enough food is left over to fight hunger among free people all around the globe." (H. Doc. No. 73, 89th Cong., 1st sess.)

And as Vice President Humphrey noted in his remarks to the Farmers Union in March:

"The American consumer now is enjoying food at the lowest cost of any people in the world in terms of human effort expended.

"The miracle of American agricultural efficiency is leaving its imprint in every area of the world.

"We now are exporting at a $6-billion annual rate.

"Agriculture is our greatest dollar earner in foreign trade today.

"Food is power. Abundance—and the ability to produce abundance—is one of our most valuable assets of strength in the world today." (Speech of Vice President Hubert H. Humphrey at March 15, 1965, convention of the National Farmers Union, Chicago, Ill.)

My State has realized direct economic benefits from the inventions and processes which have arisen out of Government-financed research. They have enabled the forest product and agricultural industries to maintain and increase their competitiveness, in the face of substitute materials and processes. Let me mention a few instances:

1. The reversible circulation kiln, which in the words of this subcommittee "constituted a very significant contribution to the lumber producing and wood-using industries, and is now used by large and small companies to achieve "great improved moisture quality control * * * (for) about 40 percent of the total lumber produced in the United States."

2. The plywood processes called impreg and its compressed counterpart, compreg. Manufacture of these materials under Department license is now a multi-million-dollar industry.

3. Of great interest is the turpentine derivative patented by the Department, and which is now licensed to at least three companies and is produced commercially at the rate of over 2 million pounds per year with a market value of over $1 million. This substance accounts for virtually all synthetic rubber for automobile tire treads. (Source of this material: "Patent Practices of the Department of Agriculture," preliminary report of the Subcommittee on Patents, Trademarks and Copyrights, 87th Cong., 1st sess., pp. 37–39.)

As an appendix to my remarks, I will place in the record a description of other Agriculture Department inventions which have substantially benefited the lumber industry, one of which accounts for about 7 percent of all woodpulp production.

I am impressed also by the benefits which the Southern Utilization Research and Development Division has brought to the cotton industry by virtue of the 23 patents it has obtained. The cotton carding apparatus, which Time magazine declared to be "the first major improvement in cotton carding equipment in 60 years," has resulted in a savings of between 2 and 5 percent. This has eliminated 50 percent of the usual waste and saved more than $40 million annually for the U.S. cotton textile industry.

The Department has also registered outstanding successes with the development of wash and wear and wrinkle resistant finishes. These processes account for the use of about 800,000 bales of cotton, and according to a report to Secretary of Agriculture Ezra Taft Benson continued "to hold the greatest promise for expanding or retaining markets for cotton." (Utilization and Research, U.S. Department of Agriculture, October 14, 1960.)

Other patents cover the discovery of a process to make cotton flame resistent. During World War II alone, the military used more than 700 million yards of flame resistant fabric and the potentiality for this type use is unbounded.

TITLE POLICY DOES NOT IMPEDE COMMERCIAL DEVELOPMENT

In 1960, the patent policy underlying these advances was examined for the then Secretary of Agriculture, Ezra Taft Benson, by Roy C. Newton, retired vice president for research of Swift & Co., one of the largest food processing concerns in the world. Mr. Newton's remarks on the question of the relation of title policy to commercial utilization are very interesting, and I quote: "(the only complaint that) has to do with domestic patents arises from the fact that a company cannot get even a temporary exclusive license to compensate it for the expense of commercializing a product of the (Department of Agriculture). These people will say that it inhibits the very objective of the research which is to market new products of agriculture, because no one will put up the necessary capital for such a new venture without some exclusivity to protect it. A few leading questions, however, usually develop the fact that they will go into the venture if their competitors are making a success out of it and if the invention is good enough to be very promising to their competitor, they will try to beat him to it. It is doubtful, therefore, that this policy is a serious handicap to commercialization of new developments by utilization research." (Department of Agriculture Utilization of Research.)

This is how a spokesman of big business, in a position of governmental responsibility appraised the Agriculture title patent policy. The Department itself pointed out to this committee in 1961 that the policy of reserving title and granting free access by licenses best serves the public interest by making the benefits of its research "freely available to the farmers, food processor, consumer, farm product manufacturer, and all of the members of the general public." (Patent Practices Report, p. III.)

This story of the title policy of the Agriculture Department which has had an opportunity to mature during the 30-year period that our generation has been in the Senate, and has been an outstanding success in every sense of the world. Are we now at the point where we should turn our backs on what this wise policy has accomplished?

A glimpse at the future of agricultural products as raw materials for the chemical industry, provided in the Industry & Engineering Chemistry Magazine in May of 1962, convinces me that we are not. The magazine pointed out that industry has, in the past, done a good job in utilizing agriculture byproducts such as cotton linters, soy bean oil, and tall oil from pine trees under patents assigned by the Secretary of Agriculture. In fact, it estimates that the value to commercialized products and processes under these Government patents amount to about $2.5 billion as against the total cost of research plant and facilities and operations of about $170 million. This is a ratio of return upon invested capital of 14.7 to 1.

But we promised to look ahead. The article states: "From the chemical industry viewpoint, the future holds tremendous potential for using greater amounts of agricultural raw materials. Most segments of the industry believe that the ready availability, low average cost, and presence of chemical configurations obtainable in synthetics only a high cost (or not at all) will lead to increased chemical uses for certain agricultural uses.

"Opinion is virtually unanimous that all realization of the potential of agricultural raw materials hinges upon a continuing and vigorous program of research and development."

Mr. Chairman, these developments on the horizon promise to make our agriculture even more the wonder of the world, and they can make the wonder state a participant in this exciting story.

If the title policy of the last 30 years had not existed, the picture would not be so bright. If it is reversed now, it would be a great disservice to our States and their people.

A similar Government title policy with free access by licenses was adopted by the Tennessee Valley Authority. As a result, this Nation leads the world in technology of fertilizer production. I think it is interesting to note that there are half dozen plants in the State of Arkansas which are using one or more TVA licenses on fertilizer as the basis for their entire operation, and there are nine companies in Arkansas which receive quantities of TVA-produced fertilizer materials for direct distribution, or for upgrading of their own products. A list of these concerns will also be made available.

A similar story could be told, I suppose, in nearly every State of the southern region of this country, and I believe that this subcommittee holds the proxies of

their southern colleagues when it comes to changing the patent policy of the Tennessee Valley Authority. It occurs to me that many of these Senators will have something to say in their own right should this matter come to the Senate floor.

S. 1809 WOULD UNDERMINE ACCEPTED ATOMIC ENERGY POLICY

Now may I comment on the patent policy of the Atomic Energy Commission, which surely has international and national implications as well as regional and State ones. I recall on July 17, 1954, during my first speech on "The New Giveaway: Atomic Energy," when I asked the question: "Are we to make use of the lessons taught by those great liberals who have gone before us, who in their day, too, were attacked and abused as dangerous, creeping socialists, who were charged with an attempt to set up some type of state economy, when all they were trying to do was to write into the law checks which would protect the public interest of the people of the United States against a private utility monopolistic combine."

At that time I quoted a newspaper columnist by the name of Thomas Stokes who wrote in the Washington Star of July 16, 1954:

"It may sound somewhat melodramatic that Congress is on the eve of one of the great legislative decisions in its long history.

"But that hardly seems an exaggeration * * * unless the bill as it was presented to the Senate * * * is amended to protect the public against the monopoly that some experts believe is inherent in its patent and other provisions, then future generations may be in for a lot of headaches."

The fight that we made at that time was similar to the fight to withstand private attempts to take over the Grand Coulee site and the Muscle Shoals damsite. I said then, and I feel now, that: "We are fighting for expanded free enterprise economy which requires the efforts of the Nation to harness the waterpower and the atom to produce low-cost waterpower and the other blessings they bestow. We are fighting for the people's right in their streams and the technology developed with their taxes."

In 1954 we were successful: we followed in the great work of George Norris and Theodore Roosevelt, Gifford Pinchot, Charles McNary, and Dill and Couzens and Senator George of Georgia. The seeds of this policy are just beginning to bear fruit. I should like to place in the record as appendix II an article from the Wall Street Journal of July 20, describing the proposal for construction by a private company for the State of New York of a multipurpose surfside reactor on Long Island. This plant will not only generate power, but purify a million gallons of water a day, and produce isotopes for medical uses.

I stated in 1954 and would like to state again:

"I would like to know whether there has ever been a finer example of that kind of cooperation directed at full use of resources of a region and to build up a region and to build up our great country that is found in Tennessee Valley Authority or the Bonneville Administration * * *.

"These programs enjoy the real American concept of progress in which the Federal Government as a partner provides only its services which the local people could not perform well or could not perform at all themselves. Never had the people found any programs so well calculated to foster and simulate and support a healthy flowering of private enterprise throughout the country.

"Backward peoples throughout the world [have been] flocking to our shores to learn how to follow our pattern * * * [as] an important key to achieve a higher and better civilization." (Congressional Record, vol. 100, p. 12147.)

And I can add our atomic energy development, under a "title" policy to this list. Thirty years from now, when desalinized water, and abundant power for the developing nations of the world become increasingly critical, the wisdom of the Congress in the field of atomic energy will surely be cataloged as "one of the great legislative decisions of its long history."

Is this the kind of policy the Congress should reverse by a "technical amendment"?

I read with interest the statement by Dr. Hornig at page 33 of the transcript implying that this reversal would benefit the public interest, since the agency could compel contractors to insure licensees and there is a possibility of the AEC taking title to more patents on nonatomic byproduct patents.

Dr. Hornig does not mention, however, that the Atomic Energy Commission is strongly opposed to S. 1809, and feels that section 152 of the Atomic Energy

Act of 1954 "should not be repealed." (AEC letter to Hon. James O. Eastland, dated June 30, 1965, p. 4.)

The AEC cites, in support of its position, "a comprehensive study" based on "extensive hearings" by the Joint Congressional Committee on Atomic Energy resulted in the approval of the basic "title" policy of 1954 and certain amendments in 1960. In addition, the Joint Committee has reviewed the Presidential patent policy of 1963, and recommended no changes.

As far as I am aware, the proponents of reversing this policy have advanced no evidence or authority whatever.

SECTION 11 IS UNSOUND AND UNDESIRABLE

In addition to the agriculture, TVA and Atomic Energy title policies, which have proven their worth many times over, there are other "title" provisions of more recent vintage, which are still in their infancy, but are bright with similar promise. We have the Space Act, the National Science Foundation Act, the Coal Research and Development Act, the Saline Water Conversion Act, and the Arms Control and Disarmament Act. There is the Water Resources Research Act of 1964, where a title policy might enable us to cope more rapidly with the pollution that has contributed to reducing the duck breeding population to a record low. (Daily Congressional Record, Aug. 12, 1965, p. 19407.)

Through all of these congressional enactments runs the thread of the public interest. We have new fields of technological opportunity which are being opened up by investment of the taxpayers money, accompanied by a patent policy which makes available information and inventions to all—not just the one company which was paid a profit to do the original research job. These programs listed in section 11 have been and are now major building blocks in our strength, character, and fame as a nation.

Yet, they are all scheduled for the guillotine under S. 1809, without the benefit of trial or even indictment. For Congress to act in this manner is not sound in law, in economics, in policy, or in legislative procedure. Further, in my judgment, to allow this consistent line of successful public interest patent legislation to be put to death quietly and in the dark, under the heading of "technical amendments," is inequitous. Adoption of such a provision by this body would be a breach of faith with the past as well as the future.

On the contrary, the Congress should build its policy for the future on these monumental achievements of the past.

PROPERTY DISPOSITION STATUTES OF THE PAST HAVE SHAPED OUR NATIONAL CHARACTER

While I am on the subject of the wisdom of Congress in molding our national character, I would like to invite the attention of the subcommittee to the analogy between the disposition of public R. & D. property and the guidelines for disposition of real estate in the public domain.

In 1785 and 1787 the Northwest Ordinances established the pattern for ownership and use, as well as the political organization, of our western territories. It is recalled with pride that Thomas Jefferson, the principal author of these laws, provided that the new territories would affiliate with the United States not as colonies, but as free and equal States. Further, it was decided that ownership of 1 section out of each 36 in a township would remain in the Government for the support of common schools. This Government acreage was later raised to 2 in 1848 and to 4 during the 1890's.

In 1862 the Homestead Act established a policy in accordance with President Lincoln's devotion to democratic ideals, which allowed any person to obtain a homestead of 160 acres by living and working on it.

In 1862, also, the Morrill Land Grant College Act endowed each State with 30,000 acres for each Member of Congress for the support of agriculture and mechanical institutions of higher education.

I believe that this wisdom of these policies for the disposition of the public domain have brought independence of livelihood and of mind to our people and honor to our Nation. It is interesting, I believe, that the land disposed of to further common schools, including the land-grant colleges is about the size of the

States of New Mexico and Montana.[1] It is also interesting that the amount of public land granted to small holders under the Homestead Act and its successor legislation amounted, as of June 30, 1963, to an area equivalent to the area of the States of Arkansas, Michigan, North Dakota, and Texas combined.[2] Since these figures are 2 years old, we might even be able to squeeze in Hawaii by now. (See the "Public Lands, Studies in the History of the Public Domain" by Vernon Carstensen, University of Wisconsin Press, 1962.)

Now, Mr. Chairman, we know how much this land was worth in 1862, because it is set forth in the Homestead Act—between $1.25 and $2.50 per acre. Even using the $2.50 figure, the maximum worth of all of this land in 1962, the total value of the property disposed of by the 37th Congress amounts to less than a billion dollars. Look at the good that has been done by disposing of this $1 billion worth of public property in the interests of all the people. By 1954, total investment in atomic energy had reached a cumulative total of $12 billion. In 1964, our public investment in patent property reached about $15 billion a year.

In this discussion, I am assuming that the patent rights to this public property are worth its cost—what we are spending on it. The patient rights may be worth less, or they may be worth a great deal more. The record is, I believe, deficient in this respect. The Congress needs some expert testimony on what this property is worth, and I recommend the subcommittee obtain such testimony.

At any rate, between 1947 and 1963, the Congressional Record reflects that about $85 billion of the taxpayers money had been spent to create public R. & D. property. (Congressional Record, Mar. 9, 1965, p. 4420.)

In the next 6 or 7 years, the Congress will probably appropriate an additional $100 billion for this purpose—an amount equal to our entire national budget.

THE MAIN ISSUE: HOW WILL THE BENEFITS OF THIS PUBLIC PROPERTY BE DISTRIBUTED?

Distribution of this wealth of intangible property rights is the central issue in this controversy. The issue is not how fast inventions are developed, or how much profit is made on them. This is what the business interests, whose responsibility is to be concerned with such matters, would like to have us believe.

This is the argument that Dr. Hornig comes back to again and again in his testimony,[3] that companies must be granted exclusive patent rights as incentives for commercial development. From this emphasis, you might suppose that this was the only important issue, or, at least, the most important. It is put forward as the overriding reason for the Government's parting with title to $15 billion worth of property a year.

On the question of commercialization, I am aware of no evidence which would contravene the conclusions of the Agriculture Department that a title policy is not a barrier to commercial development. I might say that, in my opinion, a self-serving statement by a contractor in this regard is not entitled to the same weight as a study, where contractors have been cross-examined, and other facts adduced.

EXCLUSIVE LICENSE SYSTEM A GREATER INCENTIVE THAN PATENTS

However, even if the subcommittee remains in doubt on this point, and believes that additional incentives are needed, Mr. Chairman, I ask the subcommittee whether the writing of incentive provisions is not a simple matter? Isn't it possible for a bill to provide, with great ease, for furnishing contractors with incentives, and also protection, by means of exclusive licenses to identified patents? Could not these licenses extend for 3 or 5 years, subject to renewal if the contractor shows he is making an effort to develop the patent? I submit that formulating such a system would be child's play for this committee.

May I ask further—would not such an approach have the advantage of retaining our successful "title" provisions of the past, and the additional advantage of almost unlimited flexibility in the future, as to the terms and conditions of licenses to be granted?

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[1] 78,600,000 acres for common schools and 9,290,000 for land-grant colleges or 137,328.1 square miles compared to 121,666 square miles for New Mexico and 147,138 for Montana.
[2] 287,300,000 acres or 448,906.24 square miles.
[3] Transcript, pp. 11, 12, 13, 14, 16, 17, 20.

If the subcommittee is most concerned with incentives for rapid development of inventions, I submit that such an exclusive license system is an even more powerful incentive device than exclusive patent rights, because the contractor is obliged to come back to the Government and make an affirmative showing of progress in order to retain his preferred position. Another benefit is that the Government agency does not need to bear the expenses of monitoring or enforcing "walk-in" rights. I suggest we let the recipient of the benefit walk in periodically, rather than making the taxpayer bear the additional monetary burden of bringing him in. I urge that this alternative receive appropriate consideration.

CONSIDERATION OTHER THAN INCENTIVE

However, incentives are not all we are worried about. The Justice Department unmasked the current version of this mythology in its dissenting opinion to the annual report of the Patent Advisory Panel of 1964. The Justice Department stated:

"(3) the report assumes that any commercial development or any invention by anyone is per se a public benefit. The Department of Justice disagrees with such an assumption. When the inventions are used to extend and consolidate commercial monopolies which go far beyond the scope of inventions or any group of inventions, we regard the public interest as having been seriously injured." (Memorandum from the Department of Justice representative, Patent Advisory Panel, Federal Council for Science and Technology, Dec. 4, 1964.)

JUSTICE DEPARTMENT'S CONSISTENT ADVOCACY OF A TITLE POLICY

In this connection, I should like to invite the subcommittee's attention to the opinion of the Attorney General in the most comprehensive Government patent report that has come to my attention, the "Investigation of Government Patent Practices and Policies." This study was begun at the request of President Franklin D. Roosevelt in 1943 and during its course, data was collected from 14 Federal agencies and 10 national governments. That study, and its supporting documents, were ultimately published in 1947, and have formed the foundation for a position in favor of a "title" policy, which the Justice Department has adhered to from that day to this. I will submit as appendix III these consistent expressions of policy by Attorney Generals since 1956—Democrats and Republicans alike.

The relevant findings and conclusions of the 1947 study are an excellent summary of the public interest factors over and above rapid utilization. They read as follows:

"IV. INVENTIONS MADE BY GOVERNMENT CONTRACTORS

"1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free enterprise."

THE REAL PARTIES IN INTEREST

The "big show," as I believe I have made clear, is how the benefits of this public property shall be distributed. The matter can be traced back to the division between the Jeffersonian Democratic Party and the Federalist Party of Alexander Hamilton. It is whether the powers of Government shall be exercised for the benefit of the many, or of the few.

I believe it is important to stress that any congressional patent bill is dealing only with Government property. It has nothing to say about private research

and development. We are dealing here only with property bought and paid for by the taxpayer.

On October 10, 1963, there was issued the President's statement on Government patent policy which gives us the following perspective:

"During the past 20 years there has been a great deal of discussion and controversy of what rights the Government should acquire to inventions resulting from Government-sponsored research and development. The importance of this question has been studied increasingly since World War II with the ever-increasing and now substantial contribution the Government is making to the research and development effort in practically every field of science and technology. The debate focuses on the public interest * * *."

If I were to characterize this debate, I would say that it has been the common law, the courts, the Justice Department, and the public interest on one side and the contractors and their representatives on the other.

Lately, the traditional business interests, who are responsible to their shareholders and whose job is to make money, have been joined by a new element. These are the scientists.

THE ROLE OF THE SCIENTISTS

We have seen a good deal of speculation on the possible effects on society of the ascendancy of scientists in our national life. I believe it is germane to point out that the patent statement of 1963 which is the work of this group, contains no memorandum or law supporting its policy. It contains no empirical study based on patent practices of the agencies whose policy it proposes to change. It contains no reference whatever to the definitive report of the Department of Justice in 1947. Needless to say, there is no discussion of the constitutional responsibilities of Congress as to patent policy or the constitutional obligations of Congress concerning the disposition of property belonging to the United States.

Mr. Chairman, I submit that the Congress has an obligation to protect the country against the presumption that the scientists can do no wrong. Many of our eminent scientists are employed from time to time by large corporations and universities, which are the recipients of large amounts of Federal R. & D. money. Many of them thus have a direct or indirect financial interest in advocating the retention of patent rights by contractors or other institutions.

In addition, their areas of responsibility are not defined in terms of political localities which contain agriculture as well as industry, small business as well as large, poor areas as well as wealthy ones. They are not subject to the same influences as a man who has gained his adult experience in the field of public service, and who is impressed with a public trust. They have not seen the ebb and flow of national policy over many decades. The scientists are wizards in creating valuable R. & D. property, but when it comes to disposition of this property, it is well that the Constitution places the ultimate responsibility with public men.

CONSTITUTION RESPONSIBILITY FOR PATENT PROPERTY IS WITH THE CONGRESS

The responsibility for dealing with property owned by the taxpayers is spelled out in article IV, section 3 of the Constitution, which provides:

"The Congress shall have the power to dispose of and make all needful Rules and Regulations respecting the Territory, or other Property belonging to the United States."

Article I, section 8, clause 8, of course, gives Congress the power:

"To promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."

The chairman reaffirmed these principles earlier this year, and in opening these hearings, noting:

"In recent years the Congress has frequently considered the inclusion of patent provisions in legislation authorizing new Government research programs. It is clearly the intent of Congress that the basic guidelines of Government patent policy should be determined by the Congress."

Even so, vigilance is called for in order to remind executive agencies, private corporations, and the people of the United States of these responsibilities. It is up to the statesman in Congress to resist the powerful pressures of this hour and to reassert the interest of all the people in their patent property.

I confess to surprise in reading the portions of the Patent Advisory Panel progress report of June 1964 which purports to establish a uniform patent policy by executive action, and to review patent practices and policies of each Government agency—many of which have been established by congressional enactment—"to identify areas where, in the opinion of the subcommittee (on Regulations Review) the regulations are either in conflict with the policy statement or fail to carry out its full intent * * *" (progress report, June 1964, p. 7).

It was shocking to me that an executive department; namely, the National Aeronautics and Space Administration, would establish a patent policy by its own regulations which is not only contrary to the report, but is in direct contravention to the National Aeronautics and Space Act, enacted in 1958 by this body. I have spoken at length and in detail upon these departures from the law on a prior occasion (Congressional Record, June 17, 1965, p. 13581).

As the subcommittee is aware, NASA's current policy leaves the disposition of Federal research and development to the discretion of individual contracting officers, who can dispose of all Federal rights at the time of contracting, when the nature, extent, and value of patent property cannot possibly be known.

These kinds of trespasses on congressional intention and responsibility should not be allowed to persist. However, I have the impression that S. 1809 would merely ratify these abuses by repealing the "title" presumptions and procedures of the Space Act and leaving matters to the same administrative discretion which has created the present unfortunate situation.

THE CONSEQUENCES OF PAST POLICY

In order to legislate on this matter for the future, I think it is necessary to assess the effects of what we have done in the past, in terms of the distribution of benefits of taxpayer-financed research.

It is my view that Congress use its power to protect public R. & D. property for the benefit of the many—the taxpayer, the small businessman, the State and municipal governments which must provide services to the people, the hospitals, and other such institutions which do not participate directly in the allocation of the $15 billion annual R. & D. appropriation.

The subcommittee may have seen the article in the Washington Post of July 17, 1965, headlined "L.B.J. Prods Cabinet for Budget Economy." I have attached it to my statement as appendix IV.

The article notes that, for the second straight day, President Johnson spoke personally with Cabinet and other officials about economy in Government.

He said: "I want each of you to bear in mind that the great burden of Federal taxation is not on the rich of this country, not on the poor of this country, but on the average family * * *. It's the average family that's going to pay the bill. They are the ones that buy the missiles. They are the ones who pay for the chauffeured limousines * * *."

Similarly, it is the average family who paid for $15 billion worth of research and development last year, and $85 billion worth since World War II, and the average family should get some return from it.

CONCENTRATION IN INDUSTRY GROWS WORSE

As to the small businessman, it seems to me from the following information developed by the Council of Economic Advisers, the Bureau of the Census, and the National Science Foundation, that the overall effect of Federal patent policy during the post-World War II era has been to reinforce and accelerate trends toward concentration in our economy.

The Council of Economic Advisers had this to say about trends in industrial structure in its annual report to the President in January 1965:

"* * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole * * *.

"The market share of the 100 largest U.S. manufacturing firms has grown rapidly * * * between 1947 and 1962, their share of value-added in manufacturing grew from 23 percent to 32 percent. And their share of all manufacturing assets increased from 39 to 45 percent between 1950 and 1962.

"(Since 1948, the FTC) has recorded more than 11,000 mergers * * *. Since 1950, the 200 largest industrial corporations have acquired more than 2,000 other concerns, and 257 of the largest 1,000 manufacturing corporations have disappeared through merger. (Economic Report of the President, released Jan. 28, 1965, pp. 132–133.)

As several members of this subcommittee are well aware, the Federal Trade Commission estimates that trends toward concentration are becoming even more pronounced. It has testified that the share of manufacturing assets held by the 100 largest manufacturing companies rose from 38.6 percent in 1950 to about 45 percent in 1962 and perhaps as high as 48 percent in 1964. The share of the 200 largest seems to be increasing even faster. (See "Economic Concentration," hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, July 2, 1964, p. 121.) The Commission says further that mergers for the first 6 months of 1965 are running at an alltime high rate of 991. (See, also, "Mergers and Superconcentration, Acquisitions of the 500 Largest Industrial and 50 Largest Merchandising Firms," staff report of the Select Committee on Small Business, House of Representatives, Nov. 8, 1962.)

Now, in the face of these tendencies, which the Justice Department has viewed with alarm under both Democratic and Republican administrations, what has been the impact of Federal research and development policy?

FEDERAL R. & D. POLICY HAS ENCOURAGED CONCENTRATION

For a beginning, we will take allocation of Federal R. & D. money to the top four companies of all industries and compare this with how industry itself allocated its R. & D. money. Between 1958 and 1962, concentration of research and development funds spent by the top four in industry declined 14 percent. Over the same period, the concentration of federally financed research and development increased 16 percent, a difference of 30 percent. For the leading eight companies the industry concentration ratio declined 4.76 percent, but Federal research and development concentration ratio increased 9.52 percent, a net difference of 14.82 percent. This is shown by the following chart, which is to be included in the National Science Foundation publication entitled "Funds for Basic Research, Applied Research and Development in Industry, 1962."

TABLE 1.—*Funds for R. & D. performance of selected groups of manufacturing companies with the largest R. & D. programs as percent of total for all manufacturing companies performing research and development, 1958–62*

Selected groups of companies ranked according to size of R. & D. programs (based on total funds for R. & D. performance) [1]	Percentage of total for all manufacturing companies																	
	Total funds for R. & D. performance					Changes in concentration	Federally financed R. & D. performance					Changes in concentration	R. & D. performance financed by company and other non-Federal sources					Changes in concentration
	1962	1961	1960	1959	1958		1962	1961	1960	1959	1958		1962	1961	1960	1959	1958	
						Percent						*Percent*						*Percent*
First 4 companies	22	22	22	22	20	+10.66	29	32	28	29	25	+16.00	12	9	13	13	14	−14.28
First 8 companies	35	34	34	33	33	+6.66	46	45	42	41	42	+9.62	20	20	23	22	21	−4.76
First 20 companies	55	54	54	54	54	+1.85	68	66	65	68	68	0	38	38	36	33	36	+5.55
First 40 companies	69	69	68	68	68	+1.47	84	84	83	86	84	0	49	50	48	43	46	+6.52
First 100 companies	80	81	81	81	81	−1.23	93	92	92	94	93	0	64	66	65	62	64	0
First 200 companies	87	88	88	88	87	0	96	96	96	98	96	0	76	78	76	73	75	+1.33
First 300 companies	91	91	92	91	90	−1.11	97	97	97	99	97	0	82	84	83	79	80	+2.50

[1] Companies were ranked individually for each of the years. Therefore, particular companies comprising the selected size groups may have changed from year to year.

This data is confirmed by reference to the data on an industry-by-industry basis. In areas where comparisons are available, the most recent (1962) figures indicate that, for the top 4 companies, the proportion of Federal money exceeds the proportion of private money in 10 cases, while one comparison is the same, and the other differs by 1 percentage point. For the top 8 companies the concentration of Federal research and development money exceeds industry concentration in 16 cases out of 19, and for the first 20 companies, the Federal concentration exceeds the industry by 14 to 4.

What is even more disturbing is that this concentration has become worse as the years have gone on and Federal research and development expenditures have risen sharply.

A comparison of the 1962 figures with the relative concentration figures of 1958 indicates the following:

"In industry, concentration of research and development funds has gotten worse in 7 cases, better in 42 cases, and has remained the same in 3.

"For Government research and development funds, where figures are available, there has been a worsening of concentration in 9 cases, an improvement in only 16, while 2 have remained at the same percentage levels."

This is illustrated by another chart comparing figures developed by the National Science Foundation for the years 1958 and 1962.

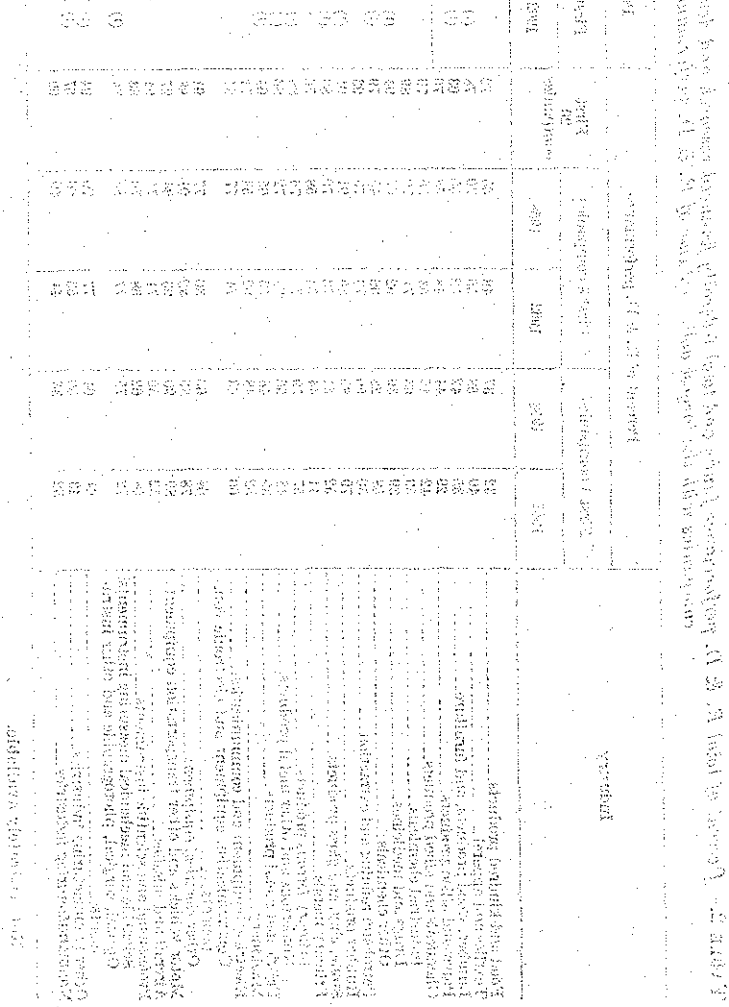

TABLE 2.—*Percent of total R. & D. performance funds and total federally financed research and development accounted for by the 4, 8, and 20 companies with the largest dollar volume of R. & D. performance by industry, 1962*

Industry	Percent of R. & D. performance					Percent of federally financed R. & D. performance				
	First 4 companies		First 8 companies		First 20 companies	First 4 companies		First 8 companies		First 20 companies
	1962	1958	1962	1958		1962	1958	1962	1958	
Food and kindred products	32	37	48	55	72	95		97		98
Textiles and apparel	40	58	56	70	78	(1)		(1)		(1)
Lumber, wood products, and furniture	35	42	52	55	63	(1)		(1)		(1)
Paper and allied products	29	44	48	58	70					
Chemicals and allied products	42	45	53	56	70	74	86	90	91	94
Industrial chemicals	59	63	74	79	89	65	87	91	92	96
Drugs and medicines	39	39	62	67	94	(1)		(1)		(1)
Other chemicals	58	28	66	45	79	(1)		(1)		(1)
Petroleum refining and extraction	50	50	73	73	93	86	62	100	66	100
Rubber products	79	85	86	91	91	(1)		(1)		(1)
Stone, clay, and glass products	52	51	73	70	88	(1)		(1)		(1)
Primary metals	41	44	53	58	76	51	47	51	73	66
Primary ferrous products	57	59	72	76	88	(1)		22		87
Nonferrous and other metal products	48	56	68	72	86	(1)		74		81
Fabricated metal products	39	48	53	65	64	(1)	62	80	89	84
Machinery	52	48	62	58	74	64	64	77	79	90
Electrical equipment and communication	60	63	74	77	84	61	64	79	81	91
Communication equipment and electronic components	64	60	80	77	91	63	63	81	80	94
Other electrical equipment	78	89	82	91	88	89	97	91	98	94
Motor vehicles and other transportation equipment	89	90	93	94	97	91	93	96	98	98
Aircraft and missiles	52	50	71	71	94	52	51	72	71	95
Professional and scientific instruments	58	62	68	70	83	69	71	79	81	88
Scientific and mechanical measuring instruments	72	75	77	83	86	(1)	92	89	95	95
Optical, surgical, photographic and other instruments	61	64	77	79	94	(1)	63	75	81	91
Other manufacturing industries	43	60	53	66	67	(1)	57	(1)	66	(1)
Nonmanufacturing industries	32	33	44	40	60	38	69	50	73	68

[1] Not separately available.

As those interest in this field know, there are enough forces in the economy militating against growth of small and medium-sized business without adding sledge-hammer blows from the disproportionate administration of Federal research and development funds in favor of the giants in each industry.

LOW PERCENTAGE OF FEDERAL R. & D. FUNDS AWARDED TO SMALL BUSINESS

Yet, we have the spectacle of about 85 percent of all Federal research and development funds being awarded, under the system of classification used by the National Science Foundation, to "large" companies of more than 5,000 employees. "Medium-sized" companies of from 1,000 to 5,000 employees receive about 9 percent, with "small businesses" having less than 1,000 employees receiving only about 6 percent of these enormous sums. (Most recent figures from National Science Foundation, 1962.)

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 perecnt of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

CONCENTRATION RAISES ISSUE OF CIVIL-MILITARY BALANCE

To illustrate the seriousness of the concentration issue, particularly in the Defense Department, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

"The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D.).

"* * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture such concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials?" ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that in fiscal year 1962, 97 percent of DOD research awards were made on a nonprice noncompetitive basis. (Hearings, testimony of Dr. R. J. Barber, Southern Methodist University Law School, p. 52).

It should be further noted that for the same year, 10 firms received 56 percent of DOD's total research money; and for NASA, the top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists. (Hearings, loc. cit., Mar. 7, 1963, p. 56–7.)

CONCENTRATION OF PATENT ACQUISITIONS

Specifically as to patent acquisitions, a Department of Justice study for the 5-year period ending in 1956 found that, among defense contractors, the top 15 companies accounted for 3,559 patents out of 6,788 assigned, for a total of 52 percent. (Hearings, loc, cit., p. 122). I would urge that the subcommittee obtain the updated figures, and make a judgment as to the degree of correlation between R. & D. contract administration and patent acquisition.

Mr. Chairman, I have recited these figures in considerable detail because they are relevant to the question of who would receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum Federal R. & D. policy, in the administration of contracts, as well as in the allocation of patent rights, should attempt to counteract trends toward monopoly and concentration, rather than reinforce them as these policies appear to have been doing.

POSITION OF SMALL BUSINESSES SHOULD BE PROTECTED

With the formulation of a general patent bill, this committee has a golden opportunity to do something about it in a practical way. Yet, what do we find?

As you know, S. 1809 has no such small business provision. The President's Science Adviser admits at page 26 of the transcript that patent questions are "especially important" to small businesses. He admits at page 27 that the patent

right problems of subcontractors are unresolved. Mr. Chairman, in the name of the 90 percent of American firms which are small business, and the 300,000 manufacturers which are small business, we ought to give small business an even break in any patent bill.

I am not asking for preferential treatment for small business. But when, year after year, the two or three dozen largest companies in the country receive one-half or two-thirds of the research money, and take out a half or two-thirds of the patents, there is little question that this policy is preferential to big business.

In the name of all we value—independence of business enterprise, of finances, of mind, and of spirit—the Congress ought to take the time and trouble to provide equitably for small business in any patent legislation.

S. 1809, which is the principal bill before this subcommittee, is based very heavily upon the language and philosophy of the Patent Advisory Panel Progress Report of June 1964.

On page 3 of this report, we find the essence of this philosophy. You will recall the following language:

"* * * where a Government contractor is expected to build upon existing knowledge in a field of technology directly related to an area in which the contractor has an established technical competence and a nongovernmental commercial position, the policy statement stipulates that the principal or exclusive rights to resulting inventions should normally remain in the contractor * * * *this situation is perhaps best illustrated by the typical Department of Defense contract which is intended to build upon a contractor's established technical competence.* * * *". (Emphasis added.)

The statistical material above indicates what has been happening to the structure of our economy under a Government patent policy dominantly influenced by the Department of Defense. These trends threaten further concentration in the economy if this philosophy is projected into the future.

This would mean disadvantage for not only small business and medium-sized business, but all business in this country except the favored few corporate giants.

Enactment of such a policy by the Congress at this time of rapid technological change and scientific discovery would cast a pall on our system of free enterprise for generations to come.

It would assure that the top companies get bigger and more powerful, while smaller rivals would be under increasing pressure to merge, sell, or be driven out of business. It also means that many men of initiative would be denied the rights of going into business, or seeing their own businesses grow and flourish. The philosophy of this proposal thus strikes at the heart of our free enterprise system.

Accordingly, Mr. Chairman, I recommend that there be a mechanism by which small businesses can gain access to public research and development patents done by the giant corporations with public funds. Retention of title and a flexible system of licensing according to the equities involved seems to me an avenue that should be explored.

In S. 2160, a copy of which is attached as appendix VI, one system of this kind is available for the subcommittee's inspection.

DOES S. 1809 PROTECT THE POSITION OF THE TAXPAYER?

Now, at last, we come down to the individual taxpayer. How can we demonstrate how his monetary interests are affected?

In the course of the "great debate," the Senator from Louisiana (Mr. Long) has raised the case of a test developed to detect PKU, a cause of infant mental retardation. While title was in the Government, commercial manufacturers were producing this test for 1½ cents to 2 cents per baby, and making a profit. When a private firm claimed a patent on this test, it was priced at $0.52 per baby.

On August 12, 1965, two Senators introduced a bill (S. 2402) that would appropriate "such sums as may be necessary" to buy a test for every newborn baby in the country. A little arithmetic demonstrates that the sums necessary would be more than $2 million higher under a license policy than under a title policy. Since the original appropriations for developing the PKU test are estimated to be about $1 million, it can be seen that a failure to take title would result in the taxpayers being charged $2½ million every year for something they had already bought for $1 million.

The details of this story are more fully set forth in appendix VII, attached, as I believe they are especially pertinent in view of the members of the Judiciary Committee who have taken an interest in this particular matter.

I realize that S. 1809 contains a special exception for "fields which directly concern the public health, welfare, and safety." But this is a limited field, where less than 5 percent of R. & D. funds are spent.

If it makes sense to safeguard the taxpayers' investment in this area, where his Government puts up an estimated 15 percent of the research money, doesn't it make even more sense in scientific instruments, where the taxpayer furnishes 57 percent, or electronics and communications equipment, where the taxpayer's share is 67 percent, for aircraft, where the share is 89 percent. (See Federal Bar News, November 1963, p. 357.) What about education? What about housing?

How many tax cuts could be paid for by the sale or reservation of royalties on some of this extremely valuable patent property areas? Far from assisting the taxpayer in this respect, S. 1809 would prevent agencies now sharing royalties to continue to do so. (Letter to the chairman of the Judiciary Committee by Federal Aviation Agency, June 5, 1965, p. 2.)

From the foregoing, it does not appear that S. 1809 gives the taxpayer an even break. I, therefore, urge the subcommittee to seek testimony from qualified fiscal experts the effects of a general sale or royalty system.

CONTENT OF GENERAL PATENT LEGISLATION

Now, Mr. Chairman, let me comment further as to the specifics of the legislation now before the committee. I have noted that the Departments of Justice and Health, Education, and Welfare, have both expressed the opinion that further experience should be accumulated under the President's patent policy of 1963 before it is embedded permanently in the form of statutory law, and the Atomic Enery Commission opposes enactment of S. 1809. If the subcommittee does report a bill, I believe that these reservations and this lack of experience and empirical data should be recognized by making the legislation quite general and providing for collection of the needed information. I believe that a bill on the subject at this time should be governed by the following six principles:

1. A clear policy statement that Federal research and development property is a "natural resource belonging to the people of the United States," and must, therefore, be safeguarded accordingly.

2. Plain and certain penalties for the giveaway or unauthorized disposition of Federal R. & D. property.

3. Provision for preserving the many congressional patent protections that have been ordered into law over the past three decades.

4. Practical means for discouraging monopoly and concentration, and thus protecting the interests of small business and an "open economic system."

5. Clear and unambiguous standards separating and providing for private interests and the public interest in the commercial development of the property.

6. A system whereby Federal R. & D. property sought by private companies for commercial development could be sold or licensed to them for an amount equivalent to fair market value, and the same property sought by other public institutions for dedication to public purposes could be sold or licensed for half of the fair market value, wherever practicable.

The language of the policy declaration as you are aware is taken from the October 10, 1963, memorandum. In my judgment, it is consistent with settled law and sound public policy. A summary of the applicable law is attached as appendix V. The absence of such a declaration or the adoption by expression or implication of a contrary policy, would be, I believe, a historic failure by the Congress.

PROCEDURAL SECTIONS ARE AS IMPORTANT AS POLICY

Several of these provisions pertain to matters of procedure and standards. These are the vehicles by which any policy would be carried into effect, and are fully as important as the policy sections.

S. 789 is a fine example of a procedural trap. As stated by the Department of HEW, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long arduous and exceedingly difficult and in many

cases impossible task." As Dr. Hornig stated: "In short, I think it leaves too few rights to the Government."[4]

As to an appropriate standard for waiver, I would recommend the one put forward by the 1947 Justice Department report, that there might be waiver under "emergency conditions" where the head of the agency certified this was so. I believe that this standard would cover the equities of all contractors adequately, but I would be willing to change my view in the face of enough concrete evidence that it would not.

There are several standards set forth in S. 1809, under which contractors would be able to acquire exclusive rights. The principal one of these is "exceptional circumstances."

The use of this phrase in connection with patent administration by a Federal agency has been specifically considered by a member of this body, the Senator from Connecticut (Senator Ribicoff), when he was Secretary of Health, Education, and Welfare. He warned of the dangerous ambiguities in the use of this standard in the following terms:

"The phrase in 'exceptional circumstances' is relatively vague and indefinite and in the absence of any indicated criteria in the policy itself would appear to leave considerable latitude to each agency head to determine what constitutes such circumstances. While this does have the advantage of flexibility, it does have the disadvantages of exposing agency heads to the pressures of those contractors who would urge that each circumstance of hardship, however slight, represents an exceptional circumstance calling for more generous allocation of invention rights."

The phrase "special circumstances" in section 4(c) of the bill is open to the same criticism which I consider to be wholly persuasive.

As a matter of fact, the report of the Patent Advisory Panel upon which S. 1809 and S. 789 are based, admits, and I quote:

"The working experience of the subcommittee has revealed that various agencies have placed different interpretations on certain key phrases found throughout the policy statement. It is believed that unless additional guidance is given, this problem of proper interpretation would only become exaggerated if left to the unguided judgment of the hundreds of contracting officers throughout the Government. The following are examples: * * * 3. The phrase 'exceptional circumstances.'"

Mr. Chairman, I believe this confession is the best evidence the subcommittee can have to establish two propositions: (1) That the disposition of these billions of dollars worth of patent properties should be placed by Congress, once and for all beyond the power and discretion of "hundreds of contracting officers throughout the Government"; and (2) that the phrase "exceptional circumstances" is not an appropriate standard to be used in this legislation.

It is my strong feeling that the power of disposition should be given into the ultimate responsibility of the head of any agency who is responsible to the President of the United States. Every effort should be made to preserve the actuality of responsibility for the disposition of Federal patent property, rather than perpetrating a misleading appearance of responsibility.

In S. 2160, I have suggested additional provisions for public licenses and royalties, and procedures which would result in written findings by the head of an agency as to both public versus private interests and value of patent interests. These proposals might be helpful to the subcommittee in formulating the necessary standards, and I commend them to the subcommittee's consideration.

If I can further assist the subcommittee during its deliberations, I would be glad to do so.

Appendix I

Inventions of the Department of Agriculture Commercialized for the Benefit of the Lumber Industry

1. The neutral sulfite semichemical pulping process for softened chipped wood in order to obtain pulp for good quality paper from woods once regarded as unsuitable for papermaking. It was reported in the press this month that application of this process has been extended to redwood chips. The process is used throughout the country, in more than three dozen mills and accounts for

[4] Transcript, p. 37.

about 7 percent of all pulp production, with a tangible value in excess of $200 million. One of the largest uses is making corrugated board for shipping containers which are superior to those made with any other materials. It also accounts for the use of more than 1½ million cords of hardwood, most of which are too low in quality for other purposes.

2. Another agriculture patent development is the fiber-glass electrical soil moisture meter for determining soil quality for both forest and range land. Again, in the words of this subcommittee: Its results have made businesses large savings in time or agriculture research workers and improved the reliability of soil by moisture determinations."

3. The electric wood moisture indicators which are widely used by lumber producers and wood-using industries.

4. Fiberneer is a new and useful packaging material. It combines the desirable attributes of paper overlaid wood veneer with corrugated fiberboard to produce a thin and lightweight material possessing substantial compressive strength under high moisture conditions.

These components have long been used separately in the packaging industry. Because of its strength, wood containers can support heavy superimposed stacking loads even when subjected to humid storage conditions. However, an all-wood container is heavy, bulky, noncollapsible, and somewhat difficult to fasten, store, and print. Corrugated fiberboard containers are lightweight, inexpensive, provide some degree of cushioning, permit labeling at time of manufacture, and are relatively strong when dry. Under high moisture storage conditions, however, an all fiberboard container loses its strength. Thus, failure to sustain substantial stacking loads places the load directly upon the contents of the container. To alleviate this problem, the height to which the containers are stacked is generally limited, resulting in inefficient use of storage space.

The object of this invention is to provide a packaging material which has the strength and resistance to moisture of wood and the light weight, low price, and printability of fiberboard. Containers fabricated from such a material, comprising a glued-up assembly of two paper-faced wood veneer sheets separated by a corrugated fiberboard medium, provides high stacking strength even when subjected to high humidity or high moisture conditions.

5. This invention relates to a machine that produces corrugated fiberboard capable of increasing the stacking strength of containers about one-third while reducing steam energy requirements to about 10 percent of conventional operations. Also, the floor area requirements are only a small fraction of present needs.

The machine produces corrugations in the machine direction of the corrugating medium, as contrasted with the conventional across machine direction. This contributes to the increased top-to-bottom compressive strength of containers fabricated from it and to the increased speed of the manufacturing operation. The speed can be increased because it is virtually a stress-free operation and the machine provides a continuous means for applying both top and bottom face liners simultaneously. Boxes can be fabricated from it on regular slotting, scoring, and printing equipment.

APPENDIX II

[From the Wall Street Journal, July 20, 1965]

NEW YORK STATE GIVES AMF GO-AHEAD TO BUILD ATOMIC DESALTING PLANT—NOTICE PORTENDS $2,750,000 ORDER FOR FACILITY TO CONVERT DAILY 1 MILLION GALLONS OF SEA WATER

(By a Wall Street Journal staff reporter)

NEW YORK.—American Machine & Foundry Corp. said it was authorized by the New York State Atomic and Space Development Authority to begin work on a $2,750,000 contract for a nuclear-powered desalination plant.

The facility will be located at Riverhead, N.Y., on Long Island Sound, and will convert salt water to fresh water at the rate of 1 million gallons a day. It will also have an electric generating capacity of 2,500 kilowatts and will produce high-energy radioactive isotopes for industrial and medical uses.

The authorization was in the form of a letter of intent providing for the execution within 3 months of a definitive contract under which AMF will provide all basic development, design, and equipment for the project. This includes the nuclear reactor, the desalting equipment, and the electric generator.

The project will involve an additional $1.5 million for other costs. Financing is being supplied in part by a $3.5 million appropriation authorized by the State legislature. The remaining funds are being requested from the Atomic Energy Commission and the Interior Department.

Construction is slated to begin early next year, pending approval by the AEC of an application for a construction permit. The permit is required to insure that the reactor isn't a hazard to the public. The plant is scheduled to be completed by 1968.

The project has been tilted with the acronym "Surfside," which stands for Small Unified Reactor Facility with Systems for Isotopes, Desalting, and Electricity.

Water output from Surfside will be purchased by Riverhead at prices ranging from 35 cents per 1,000 gallons in the 1st year to 45 cents in the 11th and succeeding years. Electricity output will be bought by Long Island Lighting Co. for 15 mills per kilowatt hour. The New York State atomic agency plans to operate the project and amortize its investment from revenue from the sale of water, electricity, and radioactive isotopes.

APPENDIX III

STATEMENTS OF THE ATTORNEYS GENERAL ON DANGERS OF CONCENTRATION INVOLVED IN PATENT POLICY

Among the factors decided in President Roosevelt's 1947 report, the theme of monopoly and concentration as a consequence of Government patent policy has recurred with regularity and increasing intensity as Federal involvement in research and development financing has mounted over the last 25 years.

A Republican Attorney General, Herbert Brownell, 1956, declared, in the following language, his concern:

"* * * with the future of competitive enterprise, and it is important that its share of this (research activity) be administered to promote competition * * * (W) indications that run counter to the industrial trend toward concentration, but in some degree may actually enforce * * * the disproportionate share of total industrial research and development in the large firms may foreshadow a greater concentration of economic power and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants."

In 1961, before Senate Subcommittee on Patents, Trademarks, and Copyrights, and in response to questioning by the chairman (Senator McClellan), Assistant Attorney General Lee Loevinger made the following summary of arguments as to the danger of concentration:

"Senator MCCLELLAN. * * * concisely, * * * if the Government gets all the benefits it wants from a license, what is the real objection to letting the inventor or discoverer, whether an individual or industry, take the patent rights for exploitation commercially * * *?

"Mr. LOEVINGER. One, this constitutes an outright subsidy to the contractor. He gets commercial rights that have been paid for generally on a cost-plus basis by the people of the United States, (and) exploits them exclusively for his own commercial benefit. They would be rights that he would otherwise have to pay for, and they are given to him out of tax moneys.

"Two, these subsidies are given not to the least able or the financially most needful, but to those that least need them, generally to the largest, most monopolistic corporations in the country.

"Three, because of this (there is a tendency toward) increasing concentration of economic power which in turn subverts the basis policy of antitrust law. * * *

"And, four, we believe that this is going to lead ultimately to a degree of concentration that will require the Government to step in with a kind of regulatory power over these great concentrated monopolies that is nothing more or less than a precursory to or a kind of socialism, if you like. I think that the surest road to socialism for this country is through the increasing monopolization of economic power.

"This alone won't do it, of course. But this is one of the ways by which this country is most likely to reach socialism [—] not by violent overthrow of the Government, but by concentration of economic power.

"Senator MCCLELLAN. You are saying in effect that monopoly leads to socialism?

"Mr. LOEVINGER. Yes, sir." (Government Patent Policy, hearings before the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, U.S. Senate, Apr. 21, 1961, p. 198.)

Successive Deputy Attorneys General of the Kennedy and Johnson administrations have expressed this concern in similar statements. Deputy Attorney General Byron R. White, before the Senate Small Business Committee on March 26, 1962, spoke as follows:

"Many of these contractors are already leaders in their respective commercial fields. They already possess highly developed facilities and mature capacity for research. The effect of allowing such firms additional patent rights as well, tends to consolidate their already dominant positions and make their preferred status in newly developed industries even more immune to competition than it is now.

"The license policy automatically grants patents to the contractor and consolidates dominance without regard for the consequences in terms of monopoly power. The experience of the Antitrust Division has demonstrated that litigation to break up unlawful aggregations of patents and know-how is a difficult and frequently ineffective remedy. It is usually available only after considerable injury has already been suffered by the economy.

"Where title generally vested in the Government, ready access of small business to know-how as well as patent rights, is more adequately safeguarded than would otherwise be the case."

The present Attorney General, the Honorable Nicholas DeB. Katzenbach, told the Senate Small Business Committee a year later:

"The Department of Justice has frequently stated that, when inventions are produced as a result of governmental expenditure it is generally undesirable to permit the developing contractors to exclude others from the use of inventions. This is partly true in cases where the research itself is aimed at developing commercial products to promote public health, public safety, or increased productivity but, beyond these obvious examples, we believe that the Government should generally retain title * * * and rarely, if ever, should the Government agency in advance of the time when the invention is known and produced for title to be given to the contractor * * * the great defect of a policy which routinely provides in advance of inventions that contractors retain title is simply that no one can know at the time (of contracting) what it is that the Government is giving up or the contractor is acquiring." (Economic Aspects of Government Patent Policies, hearings before the Monopoly Subcommittee of the Senate Small Business Committee, Mar. 7, 1963, p. 2.)

The present opinion of the Department of Justice, dated July 22, 1965, is also contained in the record.

APPENDIX IV

[From the Washington Post, July 17, 1965]

L.B.J. PRODS CABINET FOR BUDGET ECONOMY

(By Alvin Spivak, United Press International)

For the second straight day President Johnson called in Government officials yesterday to tell them to cut costs by budget-making time.

The President, who has managed to keep the budget under $100 billion for each of the past 2 years through similar techniques, again took a personal hand in the Government's economy drive.

He has indicated there is a serious question whether the budget could remain under $100 billion next year in light of the increased cost of the Vietnamese war and his Great Society programs. For the current fiscal year, the budget is $99.7 billion, with a deficit of $5.3 billion.

At yesterday's session Mr. Johnson told a gathering of officials from various departments and agencies, "I want each of you to bear in mind that the great burden of Federal taxation is not on the rich of this country, not on the poor of this country, but on the average family."

He placed heavy stress on reduced Government costs to permit the United States to finance its world leadership in education, health, and other fields.

Interior Secretary Stewart L. Udall, Agriculture Secretary Orville L. Freeman and Poverty Program Director Sargent Shriver were among the officials who reported on their own money-saving achievements.

Mr. Johnson ended the session by urging subcabinet officials to come up with "a realistic bare bones budget" that their bosses can defend when he scrutinizes it line by line at the end of the year.

He urged each Cabinet member to make at least three suggestions that could be of use to other departments as well. Pointing to charts behind him on how the Defense Department had saved billions of dollars, Mr. Johnson said:

"You all don't work with missiles but you may find out how to save on a pencil bill, or an electric bill, or a food bill, or anything. * * *

"It's the average family that's going to pay this bill. They are the ones that buy the missiles. They are the ones that pay for the chauffeured limousines. They are the ones that pay to light the chandeliers * * *."

APPENDIX V

MEMORANDUM OF LAW APPLICABLE TO DISPOSITION OF PATENT RIGHTS ARISING OUT OF GOVERNMENT-FINANCED RESEARCH AND DEVELOPMENT

This constitutional provision is silent as to the methods of disposing of property belonging to the United States, and any appraisal of the scope of authority conferred thereby is to be obtained almost entirely from the judicial precedents wherein this provision has been construed. A thorough examination of the debates and journals of the Constitutional Conventions, the Federalist, and Story's Commentaries discloses merely that the framers of the Constitution, during their consideration of this provision, were preoccupied with the acquisition and disposition of public lands by the United States.

In *United States* v. *Gratiot* (14 Pet. 526, 531, 532–533, 537–538), wherein a litigant contended that the constitutional power to dispose of federally owned property embraced only the sale, but not the lease, thereof, the Supreme Court answered by holding that the power of disposition "is vested in Congress without limitation," and "the disposal must be left to the discretion of Congress." Again, in *Ashwander* v. *Valley Authority* (297 U.S. 289, 331–333, 338 (1936)), the Court reiterated that this—

"Consitutional provision is silent as to the method of disposing of property belonging to the United States. That method, of course, must be an appropriate means of disposition according to the nature of the property, it must be one adopted in the public interest as distinguished from private or personal ends, and we may assume that it must be consistent with the foundation principles of our dual system of government and must not be contrived to govern the concerns reserved to the States.

"The occasion for the grant (of this power) was the obvious necessity of making provision for the government of the vast territory acquired by the United States. The power * * * to dispose of that territory was deemed to be indispensable to the purpose of the cessions made by the United States. And yet it was a matter of grave concern because of the fear that 'the sale and disposal' might become a source of such immense revenue to the National Government, as to make it independent of and formidable to the people.' Story on the Constitution (pars. 1325, 1326). The grant was made in broad terms, and the power of regulation and disposition was not confined to territory, but extended to 'other property belonging to the United States,' so that the power may be applied, as Story says, 'to the due regulation *of all other personal and real property* belonging to the United States.' And so, he adds, *'it has been constantly understood and acted upon.'*" [Emphasis supplied.]

"It would seem to be clear that under the same power of disposition which enabled the Government to lease (its mineral lands) and obtain profit from sales by its lessees, it could * * * have provided for mining directly by its own agents * * * and obtain profit from its own sales."

In other decisions the Court repeatedly has acknowledged that "the Government has with respect to its own land the rights of an ordinary proprietor to maintain its possession and prosecute trespassers. It may deal with such lands precisely as an ordinary individual may deal with his farming property. It may sell or withold them from sale * * *. The United States can prohibit absolutely or fix the terms on which its property may be used. As it can withhold or reserve the land, it can do so indefinitely * * *. *The full scope of this paragraph* (art. IV, par. 3, cl. 2) *has never been definitely settled.* Primarily, at least, it is a grant of power to the United States of control over its property."

(*Light* v. *United States*, 220 U.S. 523, 536–537 (1911), citing and quoting *Camfield* v. *United States*, 167 U.S. 518, 524, (1897) and *Kansas* v. *Colorado*, 206 U.S. 46, 89 (1907)). To the same effect are *United States* v. *Midwest Oil Co.* (236 U.S. 459, 474 (1915)) and *Sinclair* v. *United States* (279 U.S. 263, 297 (1929)). [Emphasis supplied.]

According to the Statement on Government patent policy of October 10, 1963: "The inventions in scientific and technological fields resulting in work performed under Government contracts constitute a *valuable national resource.*" [Emphasis supplied.]

This declaration appears to rest upon sound principles of both law and public policy.

According to settled law, a company hired to perform identified research and development is subject to turning over the patent properties arising out of this research to any employer including the Federal Government. (*Standard Parts Co.* v. *Peck*, 264 U.S. 52 (1923): *U.S.* v. *Dubilier Condensor Corporation*, 289 U.S. 178 (1933)). Since the substance of Government research and development work must be defined before contracts are granted, the Federal Government and thus the people of the United States are, under existing judicial precedents, entitled to the entire interest in the resulting property.[1] The taxpayers' interest extends not only to a license or right of use, but to the whole ownership of any invention, patent or process made in the course of a specific research assignment.

The companies performing these contracts fully recognize this principle in the universal practice of requiring their employees to sign over rights to any patent properties. This assertion of ownership applies to inventions these individuals discover or perfect in the course of not only of these same Government contracts, but the entire term of their employment and, with at least one company, beyond their employment.

APPENDIX VI

[S. 2160, 89th Cong., 1st sess.]

A BILL To amend section 305 of the National Aeronautics and Space Act of 1958 with respect to the disposition of proprietary rights in inventions made thereunder, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457) is amended to read as follows:

"SEC. 305. (a) Whenever any invention is made in the performance of any scientific or technological research, development, or exploration activity under this Act every invention made as a result of such activity shall be the exclusive property of the United States, and if such invention is patentable a patent therefor shall be issued to the United States upon application made by the Administrator, unless the Administrator waives all or any part of the rights of the United States to such invention in conformity with the provisions of subsection (f) of this section and in compliance with the requirements of this section.

"(b)(1) Each contract and lease entered into by or on behalf of any officer or agency of the United States with any party, and each grant made by any such officer or agency to any party, under authority conferred by this Act, shall be entered into or made under conditions effective to insure that such party will furnish promptly to the Administrator a written report containing a full and complete description of, and full and complete technical information concerning, each invention, discovery, improvement, and innovation which may be made as a result of any activity undertaken or performed under that contract, lease, or grant.

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[1] "* * * Virtually all governmental research contracts mark out clearly the nature of the project; this is essential, for otherwise neither party would know what costs are pertinent to the grant and hence to be reimbursed by the Government. Since the work is thus well defined and one of the goals is to invent, the Government would, under existing judicial precedents, normally be entitled to the patents and other rights in any inventions made during the performance of the contract * * *" ("Economic and Legal Problems of Government Patent Policies," report of the Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate, June 15, 1963, p. 13).

"(2) If any such party fails to transmit any such report to the Administrator within thirty days after the date on which any such invention, discovery, improvement, or innovation is made, such party shall be liable to the United States for the payment of a civil penalty in the amount of $100 for each additional day of delay in the transmission of such report to the Administrator. Action for the recovery of any such penalty shall be instituted by or under the direction of the Attorney General, and may be instituted in the district court of the United States for any judicial district in which the defendant resides, is found, or transacts business. Process of such court in any such acttion may be served in any other judicial district of the United States by the United States marshal thereof.

"(c) No patent may be issued to any applicant other than the Administrator for any invention which appears to the Commissioner of Patents to have significant utility in the conduct of aeronautical and space activities unless the applicant files with the Commissioner, with the application or within thirty days after request therefor by the Commissioner, a written statement executed under oath setting forth the full facts concerning the circumstances under which such invention was made and stating the relationship (if any) of such invention to the performance of any work under any contract, lease, or grant entered into or made under this Act. Copies of each such statement and the application to which it relates shall be transmitted forthwith by the Commissioner to the Administrator.

"(d) Upon any application as to which any such statement has been transmitted to the Administrator, the Commissioner may, if the invention is patentable, issue a patent to the applicant unless the Administrator, within ninety days after receipt of such application and statement, requests that such patent be issued to him on behalf of the United States. If, within such time, the Administrator files such a request with the Commissioner, the Commissioner shall transmit notice thereof to the applicant, and shall issue such patent to the Administrator unless the applicant within thirty days after receipt of such notice requests a hearing before a Board of Patent Interferences on the question whether the Administrator is entitled under this section to receive such patent. The Board may hear and determine, in accordance with rules and procedures established for interference cases, the question so presented, and its determination shall be subject to appeal by the applicant or by the Administrator to the Court of Customs and Patent Appeals in accordance with procedures governing appeals from decisions of the Board of Patent Interferences in other proceedings.

"(e) Whenever any patent has been issued to any applicant in conformity with subsection (d), and the Administrator thereafter has reason to believe that the statement filed by the applicant in connection therewith contained any false representation or omission of any material fact, the Administrator within five years after the date of issuance of such patent may file with the Commissioner a request for the transfer to the Administrator of title to such patent on the records of the Commissioner. Notice of any such request shall be transmitted by the Commissioner to the owner of record of such patent, and title to such patent shall be so transferred to the Administrator unless within thirty days after receipt of such notice such owner of record requests a hearing before a Board of Patent Interferences on the question whether any such false representation was contained in such statement. Such question shall be heard and determined, and determination thereof shall be subject to review, in the manner prescribed by subsection (d) for questions arising thereunder. No request made by the Administrator under this subsection for the transfer of title to any patent, and no prosecution for the violation of any criminal statute, shall be barred by any failure of the Administrator to make a request under subsection (d) for the issuance of such patent to him, or by any notice previously given by the Administrator stating that he had no objection to the issuance of such patent to the applicant therefor.

"(f)(1) Whenever any person has made any invention which under subsection (a) is the exclusive property of the United States, such person may make written application for the transfer to such person of all or any part of the interest of the United States in that invention under such regulations as the Administrator shall prescribe in conformity with the provisions of this section. Each such application shall contain a full and complete (A) description of the invention as to which the application is made, (B) statement of the circumstances under which that inven-

tion was made, (C) statement of the relationship, if any, of such invention to any contract, lease, grant, or program of the United States or any department or agency thereof, and (D) statement of such other information as the Administrator shall determine to be necessary for a determination of action to be taken upon such application. Each application for the transfer of any property interest of the United States shall be accompanied by a sealed bid specifying the sum which the applicant offers to pay to the United States in compensation for such interest if transfer thereof is granted.

"(2) Each application made under paragraph (1) of this subsection shall be transmitted to an Inventions and Contributions Board (referred to hereinafter in this section as 'the Board') which shall be established by the Administrator within the Administration. Upon receipt thereof, the Board shall accord to the applicant opportunity for hearing thereon. Notice of hearing upon each such application shall be published by the Administrator in a publication of general national circulation at least once not less than ninety days before the date of such hearing, and a second time at least sixty days after the first such publication but not less than thirty days before the date of such hearing. Under such regulations as the Administrator shall prescribe, any person shall be entitled to intervene as a party to such proceedings in opposition to such application upon a showing of probable public or pecuniary interest in the determination to be made upon such application. Each such hearing shall be subject to the provisions of the Administrative Procedure Act.

"(3) Upon the basis of evidence received in such proceedings the Board shall transmit to the Administrator its written report thereon. If the Administrator determines, upon the basis of the report made by the Board upon any such application, that considerations of equity clearly favor the granting of such application and that the public interest would be served thereby, he may transfer to the applicant the whole or any part of the interests of the United States in the invention as to which such application was made. Any such transfer shall be made upon the payment of an amount equal to the fair market value of the interest transferred as of the time of the transfer, and upon such other terms and under such other conditions as the Administrator shall determine to be required for the protection of the interests of the United States. In no case shall such fair market value be less than the amount of the applicant's sealed bid. Each such transfer made with respect to any invention shall be subject to the reservation by the Administrator of an irrevocable, nonexclusive, nontransferrable, royalty-free license for the practice of such invention throughout the world by or on behalf of the United States or any foreign government pursuant to any treaty or agreement with the United States.

"(4) Under such regulations as the Administrator shall prescribe, any person who intervenes, in any proceeding under this subsection with respect to any patented or patentable invention, in opposition to the transfer for which application was made under paragraph (1) may in such proceeding offer evidence to the effect that the Administrator in the public interest should grant to him authorization for the use of such invention, and may file with the Administrator at the time of his intervention an application for the purchase of one or more specified interests in that invention subject to the conditions prescribed by this paragraph. Each such application made under this paragraph shall be accompanied by a sealed bid containing an offer to purchase such interest or interests in the invention for a sum or sums specified therein. If the application made under paragraph (1) with respect to that invention is denied, the Administrator shall determine whether it is in the public interest to grant one or more of the applications made by intervenors under this paragraph for the purchase of interests in the invention. If he determines that it is in the public interest to grant any such interest, he shall consider the bids made therefor by intervenors, and shall grant such interest to the intervenor who is the highest responsible bidder for such interest. Any such grant shall be conditioned upon the reservation by the Administrator of an irrevocable, nonexclusive, nontransferrable, royalty-free license for the practice of the invention throughout the world by or on behalf of the United States or any foreign government pursuant to any treaty or agreement of the United States. If, after the denial of an application made with respect to any invention under paragraph (1), the Administrator determines that it is not in the public interest to grant any interest under this paragrah, he shall return unopened all sealed bids made by intervenors.

"(5) Each determination made by the Administrator in or with respect to any proceeding under this subsection shall be made in writing, and shall be

accompanied by a report in which the Administrator shall set forth fully the facts and circumstances upon which reliance was placed in the making of that determination. Within sixty days after the final determination of any such proceeding by the Administrator, any party to such proceeding who is aggrieved by any determination made therein by the Administrator may institute action in the District Court of the United States for the District of Columbia for the review of such determination. Upon service of the complaint in any such action upon the Administrator, he shall certify to the court a true and correct copy of the transcript of all evidence taken in such proceeding and a true and correct copy of each determination and report made therein by the Administrator or by the Board. Such court shall have jurisdiction to hear and determine any such action, and to enter therein such orders as it may deem proper to affirm, modify, set aside, or enforce as affirmed or modified any determination made by the Administrator in such proceeding. In any such action, findings of fact made by the Administrator shall be conclusive if supported by substantial evidence. Upon application made by any party to any such action, the court in its discretion may order additional evidence to be taken before the court or before the Administrator upon such terms and conditions as the court may deem proper. Process of the district court in any action instituted under this paragraph may be served in any other judicial district of the United States by the United States marshal thereof. Whenever it appears to the court in which any such action is pending that other parties should be brought before the court in such action, the court may cause such other parties to be summoned from any judicial district of the United States.

"(g) To the extent to which disposition of rights to any invention has not been made under subsection (f), the Administrator shall determine, and promulgate regulations specifying, the terms and conditions upon which nonexclusive licenses will be granted by the Administration for the practice by any person (other than an agency of the United States) of any invention for which the Administrator holds a patent on behalf of the United States.

"(h) The Administrator is authorized to take all suitable and necessary steps to protect any invention or discovery to which he has title, and to require that contractors or persons who retain title to inventions or discoveries under this section protect the inventions or discoveries to which the Administration has or may acquire a license of use.

"(i) Whenever any person has appropriated to his own use or benefit any invention which under subsection (a) is the exclusive property of the United States, without authority therefor conferred upon him pursuant to subsection (f) or subsection (g), the Attorney General, upon his own motion or upon request made by the Administrator, may institute action against such person in the district court of the United States for any judicial district in which such person resides or is found. Such court shall have jurisdiction to hear and determine such action. If the court determines that any such unlawful appropriation has occurred, it shall enter such judgment, orders, and decrees as it shall determine to be required to provide for the establishment of title to such invention in the United States and for the recovery by the United States of a sum equal to the aggregate amount of all income derived by the defendant through the exploitation of such invention. Any private citizen of the United States having knowledge of any such unlawful appropriation of any such invention by any person may on behalf of the United States institute action against such person in any such district court for any relief which would be available to the United States under this subsection in an action instituted hereunder by the Attorney General. A successful plaintiff in any such action instituted by a private citizen shall be entitled to recover from the defendant, in addition to any relief granted to or on behalf of the United States, a sum equal to the aggregate amount of the expenses actually and necessarily incurred by the plaintiff in the preparation and prosecution of such action, including a reasonable attorney's fee, as determined by the court. If, in any such action instituted by a private citizen, the court renders judgment requiring the payment of any sum to the United States, the plaintiff shall be paid, from the sum so recovered by the United States, an amount equal to 10 per centum of that sum, or the amount of $50,000, which ever amount is smaller. Process of the district court in any action instituted under this subsection may be served in any other judicial district of the United States by the United States marshal thereof. Whenever it appears to the court in which any such action is pending that other parties

should be brought before the court in such action, the court may cause such other parties to be summoned from any judicial district of the United States.

"(j) Whoever, with knowledge that an invention is the exclusive property of the United States, (1) appropriates or attempts to appropriate such invention to his own use or benefit without authority for such appropriation conferred upon him under subsection (f) of subsection (g), or (2) knowingly conspires with any other person to appropriate any such invention to the use or benefit of any person not lawfully entitled to the use or benefit of such invention, shall be fined not more than $10,000, or imprisoned not more than five years, or both. Any person who commits any offense under this subsection with willful intent to defraud the United States of its right to such invention or to the exploitation thereof shall be fined not more than $50,000, or imprisoned not more than ten years, or both.

"(k) As used in this section—

"(1) the term 'person' means any individual, partnership, public or private corporation, association, institution, or other entity;

"(2) the term 'contract' means any actual or proposed contract, agreement, understanding, or other arrangement, and includes any assignment, substitution of parties, or subcontract executed or entered into thereunder; and

"(3) the term 'made', when used in relation to any invention, means the conception or first actual reduction to practice of such invention."

SEC. 2. The amendment made by this Act shall have no application to any invention made in the performance of any work under any contract entered into by the National Aeronautics and Space Administration before the date of enactment of this Act.

APPENDIX VII

DETAILED COST COMPARISONS OF PKU TESTS UNDER PUBLIC AND PRIVATE PATENT OWNERSHIP

It has been brought to my attention that on August 12, Senators Prouty and Edward Kennedy introduced S. 2402, a bill to promote the detection of phenylketonuris (better known as PKU) and other inborn errors of metabolism leading to mental retardation.

Such legislation would allow the Surgeon General to make grants of "such sums as are necessary" to the States to pay the cost of blood-testing programs and other screening examination expenses. The simple blood test used to detect PKU in infants which was developed with public funds by Dr. Robert Guthrie at the University of Buffalo, has been the subject of much discussion since it was brought to the attention of the Senate and the public by the Senator from Louisiana (Mr. Long).

Senator Long pointed out that Miles Laboratories, having secured an exclusive license from Dr. Guthrie for the life of the patent, reportedly wanted to charge $262 to produce a test kit for 500 babies. Dr. Guthrie's cost to produce the kit was $6. Fortunately, dedicated public servants in the Department of Health, Education, and Welfare became aware of this situation and determined that ownership of the invention belonged to the United States and the proper action was taken to annul the license to Miles.

If each newborn child is to be tested for PKU, and the Government is to subsidize this effort, the market for the test kits is virtually limitless; the normal risks of production are eliminated. Therefore, the customary justification for the granting of exclusive rights to produce the kits would have no merit. The projected figure for the average annual number of births in the United States over the next 5 years is 4,960,000 annually. If Miles had been allowed to sell the kit for 52 cents per child as it had planned to do, the annual cost to the Government for the kits alone under the program proposed by S. 2402 would have been $2,579,200 per year. With title to the invention vested in the Government, however, it is possible for hospitals to purchase the kits commercially for less than 2 cents per infant, and for those hospitals with adequate facilities to produce the kit themselves to do so for 1.2 cent per kit per child.

This is a difference of over 50 cents per kit per child based upon the difference between a "title" and a "license" policy.

The costs of producing kits for all newborn infants in a year under the two policies would be $59,520 versus $2,519,600.

A license policy would thus have cost an additional $2 million annually to purchase something that had originally been paid for by an estimated $1 million in appropriations.

APPENDIX VIII

THE UTILIZATION OF GOVERNMENT-OWNED PATENT INVENTIONS

Inventors indicated that the amount of necessary development for commercialization of most Government-owned patents is slight or moderate (see table 10). Approximately 35 percent of all Government-owned patents require slight development, 40 percent moderate, and 18 percent extensive.

TABLE 10.—*Inventors' estimates of the amount of further development required for commercialization of sampled patented inventions*

Agency or department	Total number	Extensive		Moderate		Slight		Blank	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Department of Agriculture	10	1	10.0	5	50.0	4	40.0	0	0
Atomic Energy Commission	22	5	22.7	7	31.9	9	40.9	1	4.5
Department of Defense	46	8	17.4	19	41.3	14	30.4	5	10.9
Other agencies	2			1	50.0	1	50.0		
Total	80	14	17.5	32	40.0	28	35.0	6	7.5

"The Utilization of Government-Owned Patented Inventions," Mary A. Holden, assistant research professor of economics, George Washington University, Washington, D.C., reprinted from the Patent, Trademark, and Copyright Journal of Research and Education, vol. 7, No. 2, Summer 1963, p. 153.

Senator MORSE. Then, sir, in fairness to you and the committee as well as other witnesses, I wish you would instruct your assistants to keep time on me and stop me at, I think, the end of 15 minutes, so that I will not exceed a reasonable time.

Senator MCCLELLAN. We will not stop you. We will alert you as to that length of time. Fifteen minutes?

Senator MORSE. I think you want me to testify for 15 or 20 minutes, and I want to be sure that I stay within that time.

Senator MCCLELLAN. No, Senator. We were just trying to expedite the hearing for the benefit of people from out of town, but we have not adhered to that rule. You may have all the time you wish.

Senator MORSE. No, I do not want to do that, because it is important that you hear the other people. I have put my whole statement in, and I know you well enough, and the committee well enough, to know that my statement will be carefully analyzed by you and the staff. That is the important thing, to get it in the record.

Senator MCCLELLAN. Very well.

Senator MORSE. I would like to say at the outset, Mr. Chairman, that I have been the beneficiary for almost 4 years now of an association with a brilliant young lawyer, who sits at my right, Mr. Herbert Spira, who is on the legal staff of the Small Business Committee. He and I have worked on this patent issue for that period of time.

I never believe in cribbing, Mr. Chairman, without acknowledging the cribbing in advance. I want to say that this is a mutual effort of Mr. Spira and your witness this morning. I want the record to show that I am very proud to present Mr. Spira for this record, so that future reference to it will show that he and I have worked together on this matter.

Since 1947, the American taxpayer has spent $85 billion on Government-financed research and development. In the next 6 or 7 years $85 billion more will be contributed by the taxpayer and appropriated by the Congress for these purposes. The commitment of public funds on this scale to scientific research and the development of advanced systems is surely one of the most significant economic events of modern history.

This subcommittee has the task of formulating national policies for disposition of the rights to the commercial exploitation of patent property created as a result of these public expenditures.

The chairman's letter of invitation to Members of the Senate is one more indication of thorough and conscientious approach which the subcommittee has taken to this extraordinary and complex task. I feel that the Nation is fortunate in having such consideration by the chairman, and the diligent participation by the members of the subcommittee, which is being brought to bear on these problems.

My formal statement is rather lengthy, since there is a good deal of statistical and historical material which I would like to have available to the subcommittee. I would like to proceed with the summary. If there is time remaining, I would be glad to go into a particular area which the subcommittee believes it would like to ask me about.

I am aware that the subcommittee is very much concerned with the commercial utilization and exploitation phase and I will place my emphasis there.

In accordance with the chairman's wishes, I have included in my statement an outline of my activities in the patent and public property areas, including the history of the Morse formula, my participation in the Atomic Energy legislation, and the legislation which I have introduced on NASA patent policy during the 88th and 89th Congresses. My position, as embodied in S. 2160 on NASA patent policy, is that taking of title by the Government in behalf of all of the people should be coupled with a flexible system of licensing, such as was discussed with Dr. Shannon on Tuesday morning, August 17. Under procedures which I envision, this system will provide equal protection, and even greater incentives than waiver of patent rights, for contractors developing and marketing inventions.

A precondition for such a flexible policy is, of course, the assertion of title by the Government agency concerned in the first instance. Once patent rights are waived to an individual contractor for 17 years, flexibility is lost forever.

At the opening session of the hearings, the President's Science Adviser gave great emphasis to this issue of utilization. My experience makes me sensitive to additional considerations of great importance. An excellent summary of these factors is found in the findings and conclusions of the Attorney General's report of 1947, which I would like to take a moment to read:

IV. INVENTIONS MADE BY GOVERNMENT CONTRACTORS

1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science;

will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free enterprise.

This work, entitled the "Investigation of Government Patent Practices and Policies," was begun at the request of President Franklin D. Roosevelt in 1943, and during its course, 14 Federal agencies and 10 national governments were consulted. It was ultimately published in 1947, and has formed the foundation for a position in favor of the public interest, which the Justice Department has adhered to from that day to this. I invite the subcommittee's attention to this document, because I do not believe it was mentioned either in the Presidential patent statement of 1963 or before this subcommittee, as it is the most comprehensive and persuasive study I have been able to find.

I believe that these considerations, together with the evidence gathered by Secretary of Agriculture Benson—cited at page 7 of my statement—that Government title does not impede the commercial development of inventions, are convincing of the value of a basic title policy for Government-financed R. & D.

However, the subcommittee is quite correct in coupling its consideration of ownership provisions with the system of utilization. The two should go hand in hand.

It is my feeling that contractors should feel that they are receiving completely fair treatment from the Government in this area, just as small businessmen, taxpayers, and individual inventors should feel that their interests are getting an even break.

In contrast to the bright successes of title policy, in the areas of agriculture, TVA, and atomic energy, let us examine the consequences of the license policy, as exemplified by the Department of Defense, and more recently of NASA. I have spent a considerable time analyzing the effects of our Government contract and patent policies on increasing concentration of wealth and assets among the Nation's largest companies. At this time, I am pleased to make these findings available to the subcommittee.

As the subcommittee is aware, the Council of Economic Advisers told the President in January that:

> * * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole * * *.

I am sorry, Senator. I have jumped over to page 10 in the interests of time. I should have told you that.

I am informed that mergers hit an alltime high of 991 in the first 6 months of 1965.

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 percent of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

To illustrate the seriousness of the concentration issue, particularly in the Department of Defense, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

> The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D).
>
> * * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture each concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials? ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that in fiscal year 1962, 97 percent of Department of Defense research awards were made on a nonprice, noncompetitive basis. (Hearings, testimony of Dr. R. J. Barber, Southern Methodist University Law School, p. 52.)

It should be further noted that for the same year, 10 firms received 56 percent of Department of Defense's total research money; and for NASA, for top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists. (Hearings, loc. cit., Mar. 7, 1963, p. 56–7.)

Now, in the face of these tendencies, which as I document in an appendix to my statement, and which the Justice Department has viewed with alarm under both Democratic and Republican administrations since 1947, the following question arises: What has been the impact of Federal research and development policy?

In brief, Mr. Chairman, the charts which appear at pages 20 and 21 of my statement show that the Federal Government is concentrating a greater proportion of its R. & D. funds in the top eight firms in each industry than private business is itself spending. The charts also demonstrate that this relative Federal concentration was worse in 1962 than it was in 1958.

I jump now, in the interests of time, to the top of page 14, Mr. Chairman.

A most trenchant analysis of the dangers in these trends was made by a Republican Attorney General, Herbert Brownell. In 1956, he declared in the following language his concern—

> with the future of competitive enterprise, and it is important that its share of this [research] activity be administered to promote competition * * *. [W]hat indications that are available warn that the Government expenditures may not run counter to the industrial trend toward concentration, but in some degree may actually enforce it. * * * The disproportionate share of total industrial research and development in the largest firms may foreshadow a greater concentration of economic power in the future. * * * (A) present concentration of such manpower and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants.

These trends are relevant to the question of who would receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum, Federal R. & D. policy, in the administration of contracts, as well as in the allocation of patent rights, should at-

tempt to counteract trends toward monopoly and concentration rather than reinforce them, as these policies have been doing.

To return to the issue of utilization, my position has been that private enterprise, as in S. 2160, should be given the sole task of developing and commercializing inventions arising out of Government-financed research.

However, there must certainly be appropriate safeguards for the economy, the taxpayer, the small businessman, and the consumer in the form of the terms and conditions on which this development is carried out. These terms and conditions now engage our attention.

Going to page 16, after the first paragraph:

Seventeen years is a long time in this era of breathtaking technological change. One company, General Electric, is fond of saying in its annual report that half of its sales are attributable to products which did not exist 10 years ago. A system where the Government takes title and provides for a liberal granting of exclusive and nonexclusive licenses would allow a more realistic period of 2 or 3 to 5 years for a company to proceed with development and marketing phases, with absolute incentives and absolute protection. At the end of such a period, the company could come back into the agency and make a showing of what it had done, as a basis for a possible renewal of this license for a renewal period.

I digress just for half a moment to say that one thing we have been on guard against is that after the Government, with the taxpayers' money, really develops the patent, if that patent is then going to be turned over to a company, and the company is allowed to put it on the shelf for a period of years, 2, 3, 5 or x period of years (because of some other developments in its own research laboratory, and that from its commercial standpoint it would rather not develop that patent), who loses? Well, the public loses, the consumer loses.

But, under an exclusive or nonexclusive license system, after the money has been spent and the research has developed the invention or the product, so to speak, then you are going to have to go ahead and commercialize it. It seems to me that the taxpayers are entitled to that procedure.

To understand my position in this whole field, you have to understand that I am concerned about putting to use immediately the results of the taxpayers' expenditure.

Not only would this give a complete flexibility as to the number of years involved, but as to other terms and conditions of the grant. For instance, there could be consideration of States and municipalities which must provide services for all of the people, and of hospitals and universities which are rendering services in the public interest. Such a system could provide for equitable access for small businesses which did not participate in the original contract for research or development. They could also provide for a determination of royalties, in certain cases, which would provide a return to the taxpayer of some of his $15 billion annual investment. An additional feature should be that the so-called walking-in provisions should require walking in by the contractor, who desires to retain a preferred position. This would save the Government the administrative burdens and expense of monitoring and enforcement. A renewal proceed-

ing would also provide an opportunity for other parties to present their views and claims on the basis of changing circumstances.

To digress again for just a short period, I am not proposing and would not support a plan whereby a company entered into a contract, developed a product or an invention that was patentable, the Government took out the patent on it, and then that patent was to be made available to everyone at that point. That is not my proposal.

I think that the contractor that did the research, although it was paid for by the taxpayers, ought to have what might be called a walking-in privilege. He ought to be able to show his contribution. That ought to be on the basis of the facts shown. He ought to get a license.

In many of those cases it would be an exclusive license for a period of 2, 3, 5 years, and at the end of that period, he could show what he had done to commercialize it. He could show what he might have done to improve it, and he would walk in again, and on the basis of a hearing and a review, if he demonstrates a justification for a continuation, his license is extended for another period of 2, 3, or 5 years.

I am not seeking to follow a course of action that is going to discriminate against the developer. At the same time, I say the public has got to be protected against giving patents for long years of patent life to the disadvantage of the rest of the economy and the rest of the businesses of our country. If this particular individual does not go ahead and commercialize and does not go ahead and continue the maximum use and development of the product.

I think my time is up, Mr. Chairman.

Senator McCLELLAN. Your time is not up, Senator, except that you asked us to advise you at the end of 15 minutes.

Senator MORSE. I want to accommodate myself to the convenience of the committee.

Senator McCLELLAN. You may continue, if you would, if you have the time. I thought you had another committee meeting.

Senator MORSE. I do. But I would like to read one or two more pages.

Senator McCLELLAN. I would just like to ask you one question for clarification before you go, if you have time.

Senator MORSE. Well, I have time. My time is yours. Don't worry about that.

Senator McCLELLAN. You have all the time you want here. I do not want you to think you are limited.

Senator MORSE. I know. You have been very kind. But it is my request to which you are responding.

I do want to take just a minute on procedure. As the chairman and the Senator from North Dakota are aware, I do not know of anyone who is more conscientious in attempting to provide fair procedure. As you have heard me say to your boredom so many years on the Senate floor, substantive rights are, after all, determined on procedural rights, and your procedure has determined in some measure what substantive rights shall be available. This is true here, too.

As the chairman knows from his long career in public life, the procedural section of any bill is just as important as the policy declaration, if not more so. My formal statement contains several recommendations as to the procedural devices, and I would like to point up a few of these.

I have been especially concerned with the status of small business under patent legislation that may be enacted. May I say that my small business philosophy is not the protective variety. I believe that we must give small business of today an even break so that they can grow up to be the large substantial businesses of tomorrow. This keeps our economy dynamic. It is particularly important in new fields which are being opened up by Government-financed research and development. Firms like IBM, Texas Instruments, or Tektronics, from my own State of Oregon, which will be testifying before you today, were all once small businesses.

In fact, may I say, Mr. Chairman, that the experience of the Tektronix firm has put them into a unique position, and that their testimony should be very helpful to the subcommittee in exploring the litigation aspects of patent utilization. I am very proud to have them as witnesses before your committee today.

That does not mean that they agree with me at all in all the aspects of my position. Nevertheless, they have a position and I know you will give a very fair hearing to, and I know they are going to make an important contribution to the record of this hearing.

The problem is now to provide access to the $15 billion products of Government R. & D., which is performed by relatively few firms, for all of the small business community. The subcommittee has a golden opportunity to do this.

I say particularly to my brother member of the Small Business Committee, Senator Scott of Pennsylvania, that Congress should take the time and trouble to devise the procedural features which will carry out this access. I say that because I know of his great interest in it.

This would not be a Republican measure or a Democratic measure but a bipartisan effort to strengthen the foundations of our economy by giving the small man a fair shake.

In S. 2160, my bill on NASA patent policy, which I have attached as an appendix to my statement, several of these procedures are set forth. I would like to advance them for the committee's consideration. Since there are few landmarks in this area, I would like to stress that these suggestions should not be regarded as definitive. These are efforts which I hope might contribute to the creation of a workable system. They include 90-day notice, a hearing, and limited judicial review, with the findings of fact of the Administrator or the reviewing officer to stand unless the court finds that they are not based upon substantial evidence.

I am about to close by going to the bottom of page 19.

I am also concerned, as is the subcommittee, with the interests of the taxpayer. The taxpayer would benefit, under the licensing system described in my statement, from increased competitiveness and lower prices of the finished product. He could also benefit immeasurably from the institution of a general policy of sale or royalty of the patent

rights in areas where this is a practicability. I have recommended in my statement that the committee secure the opinion of a fiscal expert on the amounts that might be realized through such a royalty system.

The cause of the individual inventor has also been mentioned. I believe that consideration of this legislation presents an outstanding opportunity to give greater standing and possible financial reward to the individual inventor. Any provision governing the relationship between the Government and the contractor on this point should probably be conditioned upon the relationship between the contractor and the individual employee.

To conclude, I shall attempt to sum up the directions I believe the committee should take. With respect to S. 789, Senator Saltonstall's bill, I belive it is a fine example of a procedural trap. As stated by the Department of Health, Education, and Welfare, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long, arduous and exceedingly difficult, and in many cases, impossible task."

S. 1809 is, of course, the principal bill before the committee. I commented upon the provisions of this bill in considerable detail in my formal statement. I might repeat that I consider section 11, which repeals the public-interest patent provisions of the last 30 years, to be unsound and undesirable. The current legislation, rather than reject the past, should be built on its monumental successes.

At this point I shall discontinue reading my summary, Mr. Chairman, since the entire summary has already been inserted in the record. Thank you very much.

Senator McClellan. Very well.

Senator, do you have any questions?

Senator Burdick. I am sorry I was a few minutes late, Senator. Do you think the patents should be taken in the name of the Government and then exclusive license granted in certain instances?

Senator Morse. In certain instances, exclusive license permits; in other instances, nonexclusive license permits. It all depends upon what the developer can show has been his contribution to the development, and what he is able to accomplish in getting the product on the market.

I have stressed, Senator Burdick, that if the Government is going to spend all this money, then the result should not be locked up; it should be put on the market just as rapidly as the developer can put it on the market. And he should be given a license permit if the hearing shows that he made a great contribution in its development.

Senator Burdick. What procedure would you recommend for determining when an exclusive right or a nonexclusive right or any right should be granted?

Senator Morse. Well, I would provide for a hearing where he comes in and presents his case, asking for an exclusive license, and the Government agency decides whether or not he should get it, or get a nonexclusive license.

Senator Burdick. Have you read the bill submitted by Senator Long?

Senator Morse. Yes; I have.

Senator Burdick. S. 1899?

Senator MORSE. Yes; I have worked with Senator Long over the years in regard to his patent position.

Senator BURDICK. I noticed that you did not comment on S. 1899, maybe by inadvertence. What is your opinion of that legislation?

Senator MORSE. Well, I yield to Senator Long for authoritative comment on that bill.

Senator BURDICK. On page 25 of your prepared statement, you say: "I realize that S. 1809 contains a special exception for 'fields which directly concern the public health, welfare, and safety.' But this is a limited field, where less than 5 percent of R. & D. funds are spent."

I want to advise you that yesterday a few witnesses felt that was going too far. What is your opinion of that?

Senator MORSE. Well, I think Dr. Keppel in his outline had a pretty reasonable approach to it.

We have the subject before our committee at the present time, I may say. We have not come to any final conclusion. But my tentative opinion is to support Dr. Keppel in his announcement of administrative policy, and I have expressed such an opinion on the Senate floor. (See daily Congressional Record, August 17, 1965, p. 19918).

What Dr. Keppel is saying, in effect, is what the Department of Justice has said for years, going back to the Attorney General's pronouncement of policy in 1947.

Senator BURDICK. Do you agree with the exception in S. 1809, then, in regard to public health?

Senator MORSE. Yes; I would go along with the exception.

Senator BURDICK. Regardless of modification or qualification?

Senator MORSE. Well, as I said, our Senate Committee on Labor and Public Welfare is grappling with patent amendments to various health and education bills. But I would not commit myself to any qualification or modification at the present time.

I really think the trouble is, the policy expressed as to public health and safety in S. 1809 is not carried far enough.

Senator BURDICK. That is all I have, Mr. Chairman.

Senator MCCLELLAN. Senator, thank you very much for your statement. It is quite lengthy, and I am sure it is quite informative. I assure you that the Chair will examine it with an impartial approach, insofar as I know how to do it.

Contrary to any implications that may have been made or might be made, or any aspersions that might have been cast with respect to this committee's work or the chairman, I have no preconceived ideas here, none that I could not reconsider. I have tried to approach this whole problem on the basis of an exploration, to find out what is best.

The bill I introduced, of course, as everyone knows, is largely an administration bill, at least based upon the President's memorandum of December 1963.

I have proceeded since then with a view to hearing all sides, getting all the information I could, so that we might in due course examine these different new thoughts, resolve them as best we could, and present legislation to the Senate for its enactment.

One thing that I have had trouble with, I guess we all do—and again I say that those who say this is a simple issue are not correct. It is

complicated. When you undertake to find equity and do justice, it is not easy or simple.

We have an illustration of this complexity in the fact that there may be three or four contributors involved in the financing; the talents of others; and others' skills in the research and development field.

Of course, ultimately we want to get the product, if it has value, if it has use, we want to get it into use, we want to get it to the user and the consumer. But where there is a university involved or a foundation may have made a contribution in a given area of research, where corporations or individuals may have made contributions to the university to carry on their research in that field, and then the Government makes a contribution to carry on in that field, and they come up with some discovery, how do we do equity in that situation? How do we do equity? They are joint ventures of private enterprise in which eleemosynary foundations or others have made a contribution, as well as the taxpayers. How do we do justice in handling a patent on a discovery in that situation? I don't have the answer.

Senator MORSE. I don't have the answer.

I will make a very brief observation. But before I do that, Mr. Chairman, I want to say that as far as the senior Senator from Oregon is concerned, he has said, out of your presence in many places, and is pleased to say it in your presence, that I have no question at all about the impartiality of this committee and its chairman in trying to resolve this matter on the basis of what the facts show.

I am chairman of the Subcommittee on Education, where there was a move made yesterday to add the Long amendment to the higher education bill.

Now, to divide up my attitude on a percentage basis, I suppose you would say that I lean strongly in favor of the Long amendment in the matter of education, copyrights, and in some instances with these new audiovisual patents. But I say it should not be added to this bill. We should wait until the McClellan committee finishes its hearings and comes forward with its recommendation. We should not be going off here at a tangent, and having different policies in connection with different agencies.

I think we need a governmental policy instead of having a diversity of policies such as now characterizes the handling of patents that flow from the expenditure of taxpayers' money in research and development.

Now, you raise a hypothetical situation. It is not completely hypothetical, because we can cite specific instances in which it is true. But I am talking about it hypothetically.

You raised a hypothetical situation in which you have a multiplicity of contributors to the brains, techniques, and know-how in the development of an invention or a product or other patentable item. Certainly, the patent in such a case should not be given to one of them to the exclusion of the others.

It is pretty hard, because of the nature of some of these situations. You talked about eleemosynary institutions and foundations, and Government contributions, and so on. It is always dangerous to lay down a general rule, but I am going to.

Generally speaking, I would say that in that situation your license permit program is much preferable, in my judgment, than giving what I call a frozen patent.

Now, even I as a lawyer know and Senator Burdick knows, as a lawyer, that although this is a complex problem, we do not admit that there is anything too complex factually so that we cannot at least do reasonable equity.

I think you are just going to have to have a procedure that provides for a hearing and gives every person involved an opportunity to make his case and then have the judgment rendered, providing for limited appellate review, as I set forth in my statement.

I do not know how else you are going to do it, gentlemen. I do not think you can do it by rule of thumb. Because the application of a rule of thumb without the hearing and without the opportunity to present the evidence, and without the review, I think, is bound to work injustices in those multiparty contributing situations.

So I say as a tentative answer to your questiton, Mr. Chairman, that I think it is better to have a license approach to that situation than a patent approach.

Senator McClellan. Senator Morse, I have said before that I find no way to write language into a bill to cover every situation. In my judgment, judgment ultimately has to be reposed in someone with a measure of discretion. I do not know how you are going to avoid it.

Senator Morse. You are not going to be able to avoid it.

Senator McClellan. I do not know how you can avoid it.

Senator Morse. The provisions of my NASA bill, on the basis of what you have brought out in this hearing, are going to need great modification to apply generally. I have no doubt of that. I am not married to that bill.

But on the basis of the facts that we do know about, I felt that this was a bill that ought to serve as a basis for hearing and for modification.

I think that more important than my bill, may I say most respectfully, is my statement. Because I think you will find in my statement some information that you are not going to find anywhere else—at least, I have not found it anywhere else.

As I said, we have worked on this general problem, Mr. Spira and I, for 4 years. We have tried to help the committee by bringing forth in the statement some material and trying to coordinate it with other material to help the committee form what I think would be a better public policy than we have on it at the present time.

I just do not think, Mr. Chairman and Senator Burdick, we can very well justify continuing a governmental policy of such diversity as we have at the present time, with the Defense Department and NASA going off in one direction, the Department of Justice going off in another, some of your health agencies in a somewhat modified position but still in another direction.

Now you have got this issue raised in the Department of Health, Education, and Welfare; you have got those new procedures announced by Dr. Keppel, which I think are meritorious as far as

I have analyzed them. We are going to have him come up to discuss those procedures before my subcommittee within a few days.

But what I am pleading for is an end to what I think is a diversity of treatment that is not fair, because its lacks uniformity of Government policy.

Senator McClellan. I agree with you, there ought to be an overall statute.

Senator Morse. You have got to have it.

Senator McClellan. That is all I have argued for up to now. I have not taken a final position on the immediate issue before us. I am still searching and exploring.

Yesterday there was some testimony, if I remember correctly, that quite surprised me, and I thought it pointed up one of the problems in this field. This was in the field of medicine, where they do a lot of research which result in discoveries, some of which are patentable.

It was brought out that probably 1 out of 10, only 1 out of 10 of those discoveries is ever taken down off the shelf, so to speak, and an undertaking made to process it. And out of those instances of 1 out of 10, a great many of them fail to develop into something that is commercially profitable or really beneficial.

In other words, after the discovery is made, the testimony showed here that it took from maybe $200,000 to $400,000 to test it, refine it, and get it adapted to human use and medical use, and that a lot of times some money was spent that way that never produces anything.

So, just getting a patent and getting it on a government shelf is not the answer.

Senator Morse. That is correct.

Senator McClellan. There has to be a way of providing an incentive somewhere to get somebody to put in the risk capital, try to take it and develop it and bring it into a state of usefulness and a readiness for the commercial market.

Senator Morse. You will find that I stress that in many places in my statement.

Now, there is another phase of that. You have to have an incentive. Here you have 20 research findings involving various phases of the same potential product. You also have to have a program flexible enough, in my judgment, so that you do not let "X" take it just exclusively, when "Y" or "Z" or "A" or "B" would like to make another approach to the handling of that end product as it comes out of the research laboratory, and they might be more successful than "X" in developing it for commercial uses. You have to try to find how many of them you are going to allow to have a chance in developing it.

In my final appendix, I set forth data concerning the fact which was discussed on Tuesday morning before this committee, that as we move forward—as we move toward fields where the Government needs end items the proportion of development paid for by the Government becomes very high.

For instance, there is almost complete transference between items such as military planes and the Boeing 707; and the military synchronous satellite and the Early Bird commercial satellite.

My plea is that we not get ourselves in a position where we freeze the results of this Government-paid-for research and development so

that other companies that might have scientists and technicians of a different background and interest are going to be denied the opportunity to bring their brains to bear upon the laboratory results. But at the same time, as you pointed out, you should also have an incentive for the fellow that helped develop it in the first place, although you and I as taxpayers paid for it. Therefore, give him 2 or 3 years' exculsive permit or license, see what he can do with it, and then let him come in and show what he is doing. If the other people can show that he is not doing what he ought to be doing, then make it nonexclusive rather than exclusive at that point.

Senator McCLELLAN. The point I am making, Senator, in addition to that, is this: You get the discovery, the patent; it is on the shelf. The Government now has complete control of it. As illustrated yesterday, less than 1 out of 10 has anybody manifest any interest in it. When someone does manifest such an interest, he says, "I'm going to spend $200,000, $500,000," whatever it is, "to see if I can develop this thing."

You say that others should have an equal opportunity. I agree that everybody should have an equal opportunity, but when someone selects it and says, "Now, I want to take it and try it. Nobody else has. If you will give this to me, you call it an exclusive license, I'll take it and spend some money on it and see what I can do"—you say, "Well, he may not be doing all he should. He may take it and drag his feet."

Well, you would not give him the license until he brought it into a state of usefulness, where he said it was not a marketable product.

Senator MORSE. I would not renew it——

Senator McCLELLAN. If he does drag his feet and produces nothing within 2 or 3 years, then you might very well have some limitation in time in which he has to make a development. But if you say to him, "Well, now, any time we get dissatisfied about that, we are going to take it away from you and give it to somebody else," I think it is going to destroy the incentive.

Senator MORSE. If he comes in during my administrative procedure hearing, Mr. Chairman, and shows what he can do, he is going to have it renewed and renewed. On the other hand, if he takes it and, in effect, uses his license to put it on the shelf, when others want to develop it, we will not renew his license at the end of 2 or 3 years, or whatever period you give it to him in the first place.

But there again, it becomes a question of a finding of fact as to what he has done.

Senator McCLELLAN. You have to use a lot of discretion. I do not see how you can get away from vesting discretion in a responsible authority.

Senator MORSE. You cannot possibly do it. I do not propose that we try.

Senator McCLELLAN. Well, thank you very much, Senator. I appreciate your staying long enough to answer a few questions.

Senator MORSE. Well, you are very kind of hear me. Thank you very much.

Senator McCLELLAN. I notice you have a copy of your bill S. 2160 attached to your statement as appendix VI. We will appreciate your making it available for the record.

Senator McCLELLAN. Our committee will be in recess for 5 minutes. We will resume in 5 minutes.

(Brief recess.)

Senator McCLELLAN. Dr. Seevers?

STATEMENT OF MAURICE H. SEEVERS, PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF PHARMACOLOGY OF THE UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

Dr. SEEVERS. Yes, sir.

Senator McCLELLAN. All right, Doctor. Please identify yourself for the record. I believe you have a prepared statement. You may proceed in your own way.

Dr. SEEVERS. I am Maurice H. Seevers, a professor and chairman of the Department of Pharmacology of the University of Michigan Medical School.

Senator McCLELLAN. First I would like to say I am sorry we did not get to you when you were scheduled yesterday, or the day before yesterday, I believe.

Dr. SEEVERS. It worked out all right.

Senator McCLELLAN. We have tried to move along here with all deliberate speed.

Dr. SEEVERS. It worked out all right with me, so thank you very much.

I am a physician and have been engaged in teaching research and administration in academic pharmacology since 1930, at the Universities of Wisconsin and Michigan. I am professor and chairman of the Department of Pharmacology of the University of Michigan Medical School in Ann Arbor, Mich. I received a Ph. D in pharmacology from the University of Chicago in 1928 and an M.D. from Rush Medical College of the University of Chicago in 1932. I am licensed to practice medicine in Wisconsin and Michigan.

During the last 35 years I have worked with, or served as a consultant to, many organizations which deal with the effects of drugs and chemicals upon health and welfare, both here and abroad. I have been fortunate in having had the opportunity to walk in the halls of learning, professional societies, Government, and industry, and am able to distinguish but one high level of public morality among the leaders in these several facets of American society as it relates to the public health and welfare.

I am a past president of the American Society for Pharmacology and Experimental Therapeutics.

I served as chairman of the Section of Experimental Therapeutics and for 10 years as a member of the Council on Drugs of the American Medical Association. Currently I am chairman of the committee for research on tobacco and health and a member of the committee on alcohol and addiction of the same organization, and have acted in an advisory capacity to many Government agencies.

I have served the Government as a consultant to the Food and Drug Administration, the Department of Defense, the Veterans' Administration, the U.S. Public Health Service, and the Office of Science and

Technology. I was a member of the Surgeon General's Advisory Committee on Smoking and Health, and am currently Chairman of the Committee on Behavioral Pharmacology of the National Institutes of Mental Health.

I have served as a consultant to the pharmaceutical and chemical industry for remuneration.

My principal area of competence is in the field of narcotics and drug abuse, and I served as a member of the Ad Hoc Panel for the White House Conference on this subject in 1961.

I have read the statements of the American Council on Education and of Austin Smith, M.D., president of the Pharmaceutical Manufacturers Association, concerning S. 1809. I believe the essential facts are presented fairly and rather completely in these two documents, and I will not reiterate most of their points.

I wish to comment especially on the detrimental effects on the quality and quantity of research in the drug field, not only that conducted in universities, but also in Government laboratories, and its effect on training of new scientists if a Government-take-all policy is applied to Government-sponsored research in the health-related sciences.

In the field of drug development the role of the pharmacologist differs significantly from that of the chemist, and his findings are much less subject to exclusive control. The chemist, for example, invents a new compound or develops a new process for manufacturing an old chemical, and can obtain exclusivity for the duration of the patent under the present circumstances.

A pharmacologist, on the other hand, studies the effects of new or old chemicals in animals or man in the hope of finding a cure for disease or a substance which will speed recovery or make the patient more comfortable. Usually these observations cannot be controlled exclusively. They come under the public weal.

To cite an example: In our laboratory we are studying the effects of morphine-like narcotics on the monkey in the hope that a new pain-relieving drug will be found which will be nonaddicting. During the last 15 years we have screened over 600 new drugs from all of the major domestic and foreign pharmaceutical companies. This, in fact, represents the world supply. This program is supported by contributions from over 40 pharmaceutical manufacturers through the Committee on Drug Addiction and Narcotics of the National Academy of Sciences and National Research Council. Any chemist, domestic or foreign, may submit new compounds through the secretary of this committee for study. He sends them to our laboratory for testing as unknowns under code number, and the information is channeled back to the supplier.

Under this program we are able to maintain an on-going university laboratory for research and training in this field of behavioral pharmacology. Industry retains exclusively of drug control. Under present Government policies, conducting such a program with National Institutes of Health support would not be possible since industry would not make the compounds available to our laboratory. Maintenance of a laboratory of this type by an individual company would be pro-

hibitively expensive, and this joint effort of the industry reduces the total cost of production of what may ultimately be a clinically useful compound.

I might depart from my statement to say that several clinically useful compounds have come out of this program and are currently in clinical use.

Senator McCLELLAN. Do I understand you to mean by your sentence just above there, "industry retains exclusivity of drug control," that they get the patent, they own it?

Dr. SEEVERS. Yes, they own the patent.

Senator McCLELLAN. In other words, if they send you a drug for experimentation and you develop it, they retain the patent?

Dr. SEEVERS. That is right.

Senator McCLELLAN. And you say that if the Government makes a contribution and takes that, then they are not going to send it there for——

Dr. SEEVERS. They won't send the drugs.

This is one of our biggest problems today in pharmacology and clinical pharmacology, because the industry will not send drugs into many university laboratories, because of the fact that we are supported by Government in some of our activities.

Furthermore, if we find, for example, that a drug under a certain name is metabolized in the body to create a new substance, which turns out to be the active substance, this new substance then completely wipes out everything that happened with the old one. It now becomes the useful substance. And if it is discovered in a Government-supported laboratory project, the Government holds the patent.

So industry automatically has lost its hold over that compound, simply because a new substance which is developed by the metabolism of the body now becomes a useful substance. Because of this, many industries will not send drugs into the clinical pharmacologists for drug development.

Senator McCLELLAN. Now, is the public health served or is it not served in the circumstance that you are illustrating and testifying about? Are the public health and welfare served by permitting the patent on any discovery to remain in the ownership of the one that transmits the drugs to you?

Dr. SEEVERS. We feel it is, because it is not possible, for example, for the university to develop a drug clear through to the point of marketing. We have no facilities for doing this. The Government does not have the facilities for doing it, either.

In fact, there is only one group that can operate independently of the Government or the university, and that is the industry. They have their own chemists, their own pharmacologists. They have their own drug control laboratories. If necessary, they could develop—which I think would be exceedingly unwise—their own clinical facilities in a group of smaller hospitals which are not university associated.

Senator McCLELLAN. This would have its impact on the university, would it not?

Dr. SEEVERS. Not only on the university, but an impact ultimately on the public health, for the simple reason that most of the smaller

hospitals, even though the doctors are qualified, are not qualified in the problem of drug development. They do not have the facilities to carry on the laboratory work that is necessary in relationship to it.

Furthermore, it would in the long run interfere seriously with this problem of the ultimate public health, as far as new drugs are concerned.

I might say just for your own information that 90 percent of all the drug information that we teach medical students today did not exist 40 years ago, and 70 percent of it did not exist 20 years ago.

This was brought about largely by the fact that we had a strong cooperative program of Government, industry, and universities, during the war. The large antimalarial program, and the large program associated with the development of chemical warfare promoted such a large chemical development that many of these compounds naturally were found to be biologically useful. This effort, of course, involved everybody's dropping what they were doing to work on these major programs to aid the war effort.

This, then, was probably the best example of a large cooperative effort even though it was not voluntary.

I think there are still some people that believe that all drug development should be carried on on this basis. This could be done in wartime; but today, to get this kind of cooperation requires that it be done voluntarily. It means very simply that the interests of everybody have to be engaged, there has to be mutual respect and confidence between industry, Government, and the universities.

I do not think it is possible to administer or legislate or regulate or coerce this type of research. It never has been in the past, and I think real cooperation is always on a voluntary basis.

I might depart further from my statement simply to say that the pharmacologist is not particularly interested in exclusivity of control. We are interested basically, as individual scientists, in getting new compounds to study biological processes. Most of these are not subject to patent, anyway, except as use patents and they are not as useful as invention patents.

One other point I would like to make, which I think has not been brought before you, is that a patent in the drug field today is not worth too much, anyway, except for a short-lived term of exclusivity. The movement today in the drug field of the development of new chemical compounds is so fast that about the time a drug reaches the market, a better one is on the drawing boards, and in a year or two it will supplant one that is currently marketed.

Senator McCLELLAN. Let me ask you a question at this point. What profit is there to the Government and the public, the people as a whole, for the Government to take that patent or that new discovery and put it on the shelf?

Dr. SEEVERS. I didn't quite understand you. What does the Government gain?

Senator McCLELLAN. Yes. What would the Government profit out of it, what would the public profit out of it, if as you say, by the time you got that drug well developed and on the market, a new one will be coming along that would probably be a better one and take its place, then, not within the 17 years in the patent statute, but maybe 2 or 3 years after it first hit the market?

Dr. SEEVERS. I think the 17-year matter is completely unimportant in this field.

Senator MCCLELLAN. It has no applicability?

Dr. SEEVERS. The Government would not profit very much, to answer your question directly.

Senator MCCLELLAN. Well, the point is, if the Government takes it, and then somebody according to some of the proposals here was able to get an exclusive license to further develop, refine, and put it on the market, by the time they would do that, the Government would give them the license, for a period of 2 or 3 years, and they wanted to spend $200,000 or $300,000 on it, somebody else might come along with another drug or an improved product that would destroy their market for this one.

Now, who gains and who loses by that sort of thing?

Dr. SEEVERS. Well, my feeling is—and this is not derogatory of the Government—that by the time this gets through the wheels of redtape, there would be two or three new drugs on the market that would be better than the one that they had a patent for.

Senator MCCLELLAN. Well, this is the point I am trying to examine: Although the Government may have made a contribution to the processing and exploration that discovered the drug, the formula, the compounds, however you refer to it, although it may have made a contribution, that is the taxpayers' money, now you have the thing and it becomes a discovery, a patentable discovery that may have useful benefits, and the Government takes it. As you point out, by the time a private firm could get that drug well advertised and on the market, and so forth, some new one may actualy have come out that would be a great improvement, to the extent that this one no longer would be in demand.

Dr. SEEVERS. That is the reason it is such a high-risk industry.

Senator MCCLELLAN. It is a high-risk industry.

But the originator, in whom you are leaving the control now as you propose, would naturally exploit his product, in other words, to try to get it on the market, try to get his money out of it, and try to make a profit out of it before some new drug came along.

Dr. SEEVERS. If he does not have any incentive, this will not be done.

Senator MCCLELLAN. But if it is given to him, if he owns it for a period of time, if he owns the patent and the control of it, obviously if he spent some money on it, he would undertake to get it on the market as quickly as possible, to recover his investment and to make a profit.

Dr. SEEVERS. I think that is a very important point. Because, as I heard earlier from your statement to Senator Morse, a large fraction of the drugs that would be patented would never reach the market, simply because of the facts that I have indicated. They would not be developed.

Senator MCCLELLAN. Would there be more of them that never reached the market if the Government took the patents to all of them?

Dr. SEEVERS. I don't believe so.

Senator MCCLELLAN. Sir?

Dr. SEEVERS. I think not.

Senator MCCLELLAN. Well, I do not know whether you understood my question. Would there be more or less of them reach the market?

Dr. SEEVERS. I would say there would be less if the Government

Senator McCLELLAN. That is what I thought. Less than now.

Dr. SEEVERS. Less than now. That would be my opinion.

It is, in fact, currently defeating cooperation between industry and the universities. The university is sort of in a middle position in this.

Senator McCLELLAN. It serves both.

Dr. SEEVERS. It serves both.

As a matter of fact, you see, the university makes a tremendous contribution to this business without any incentive except the fact that the investigators get renown, maybe, for discovering a new compound. But the university doesn't get much out of this business except in carrying on its natural function of training of people.

Senator McCLELLAN. In other words, it makes no real profit out of it.

Dr. SEEVERS. The university doesn't make any significant profit.

Senator McCLELLAN. What profit it does make goes back into the public service.

Dr. SEEVERS. Exactly.

Senator McCLELLAN. All right. You may resume your statement. I just wanted to get the record pretty clear at this point.

Dr. SEEVERS. I had been speaking about our laboratory for research and training in the field of behavioral pharmacology. I cite this as a proven and useful example of voluntary cooperation between the industry, a university, and a quasi-governmental organization. In this instance a good screen is available since the monkey shows a very close parallelism to man in his response to this class of drugs. But this is rarely the case, and preliminary studies on animals must be carried through to man in order to obtain a satisfactory answer. The development of a marketable new drug is so costly in time and money that the role of the pharmacologist becomes exceedingly important. The academic pharmacologist can neither conduct developmental research nor train students in the drug field without close association with the chemist. Restrictive patent legislation by cutting off the supply of chemicals would only aggravate the acute shortage of biologically trained scientists in pharmacology, physiology, microbiology, and all of those basic fields of medicine dealing with biological responses to chemicals.

What about the chemist? For practical purposes the chemist means industry. Why not the university chemist? The answer is quite simple. Both chemists and pharmacologists are specialists. Only rarely do these specialists coincide in the same university so that a joint effort is possible. But this is not the main point. University departments of pharmacology have neither the interest, the space, nor the staff to do large-scale drug screening. This is a routine and expensive operation which is possible only in industry or government.

Take an example of the university chemist who operates under a Government-sponsored research contract. He invents a new and patentable series of compounds designed to exert a specific biological effect which may be useful in human therapy. Under current Government practices he is unable to utilize the biological screening facilities of industry formerly available to him. Since this is a trial-and-error game in which each change in chemical structure must be correlated with observed changes in biological activity the university chemist finds himself stymied in his developmental program, with no

place to get biological testing done. Even if these facilities were available, there are very few universities with chemical facilities to produce a sufficient quantity of a new drug even for satisfactory screening purposes, or with biological control laboratories to guarantee the uniform purity, stability, and reproducibility necessary in a drug before it can be subjected to human trial.

Without belaboring the point, satisfactory drug development cannot occur in the absence of industrial know-how and facilities and commonsense tells us that this will not be available for cooperative research under unwise patent restrictions.

Current NIH policies virtually preclude joint university-industry research on drugs or chemicals at the exploratory level before patent protection is assured to the manufacturer. The large bulk of drug research in medical schools is Government-supported. In operation, a department having a dozen major investigators with their students may operate 30 or 40 individual research grants from Government, industry, or health agencies, making it impossible to maintain strict cost barriers between grants with respect to animal food and care, supplies, et cetera. Furthermore, a scientist commonly studies a certain family of drugs on a single biological system. He may obtain these drugs from a dozen sources. Today a pharmaceutical manufacturer will not risk submitting an unprotected drug to such a laboratory because of the chance that it may accidlentally or otherwise become associated with Government-supported research.

As a member of the pharmacology panel which was assigned the task of reviewing the activities of the Cancer Chemotherapy National Service Center for the Woolridge committee, the results of which were published in "Biomedical Science and its Administration," we observed that Government restrictions including patent policies made it exceedingly difficult and complex for those administering this program to carry on an adequate cooperative program. Neither the Government, as evidenced by the statements of Director Dr. K. M. Endicott, nor industry, from statements to our panel, were happy about the situation. Little initiative could be taken by the industry which could contribute to the program as a whole. Old chemicals which have been sitting on the shelf for many years were channeled into the program. Some new compounds were manufactured by industry on a contract basis, with Government furnishing the specifications, but many of the real leads in the field disclosed by industry research never found their way into the program at all.

It is my view that cooperation between industry, academic institutions, and Government, which is so vitally necessary to any successful program in such a high-risk area as drug development, will not be forthcoming unless some degree of exclusivity is granted to the inventor under a broad and flexible but uniform policy. The traditional position of university faculties as arbiters of industrial and Government disputes suggests that the university may be the best instrument through which exclusivity arrangements can be administered, especially those relating to Government-sponsored research in the health field.

In closing permit me to say that I sense a rising and accelerating tide of discontent among university scientists relating to excessive governmental control of pharmaceuticals and other chemicals. This

is manifest primarily as a strain on university-industry and indirectly on university-Government relations which have flourished so well in the past in developmental drug research. In the long-range interests of the public welfare Government would be wise not to alienate further that segment of the scientific community which contributes such a substantial fraction of new concepts and ideas in health-related research.

Senator McCLELLAN. Let me say that the more we proceed in this inquiry, in these hearings, the more concerned I become about the gravity of what is involved here. You have the public interest at stake, and some argument is made that this would be in the best interests of the public, rather than some other procedure. I just do not find it easy.

Dr. SEEVERS. It is a very difficult and complex problem.

If I may comment, I have listened to your discussion with Senator Morse about the matter of uniform Government policy, and I am in favor of uniformity, but you cannot equate health research with the development of airplanes. They just don't fit in the same category.

Senator McCLELLAN. Well, what we really had in mind, what he may have had in mind, and what I have in mind is to let the Congress fix the policy. But even when you do that, I do not know any way to do equity and justice except by leaving a measure of discretion in someone, in some public official, some administrator. I do not know how you can write a statute covering every aspect of this.

Dr. SEEVERS. It is my own feeling that in the health-related sciences, the last thing we would want to have would be unwise legislation that would prevent the longstanding cooperation between Government, industry, and universities. That has really been the solid foundation on which all the drug development has been based.

This means that each one of us has to carry on our own function. The university has primarily a training function, and that of basic research and development, and the industry has to put this into practical application.

I do not think either one can deal without the other, or either can stand alone, and it would be an unwise policy which would interfere seriously with this type of development. I think it would be against the public interest.

Senator McCLELLAN. Are you familiar with the bills that the committee is considering?

Dr. SEEVERS. In a general way.

Senator McCLELLAN. Which one of the bills, in your judgment, comes nearer to carrying out the policy or philosophy that you advocate?

Dr. SEEVERS. I think the chairman's bill comes the closest to carrying on the philosophy that I believe should be followed.

Senator McCLELLAN. Would you have any specific suggestions or any modifications or amendments?

Dr. SEEVERS. Obivously, I know very little about patents, but my feeling is that some provision should be made by which exclusivity can be granted for a period of time to those that have an equity in the invention. How this is done, I think, would take fine statesmanship; and this is something that you and your committee have wrestled with a long time.

I have heard the suggestion that universities that operate under Government-sponsored research programs in which an invention occurs might be the licensor for a period of time and make this arrangement with the idea that the university would get a little out of it, and the industry would get its seed back, and the ultimate end would be the introduction of a product into the market.

Now, this seems at first blush to make pretty good sense. I don't know whether most universities want to get into this kind of business. But it at least puts it in a group of nonprofit agencies, and would at least plow back any profits into educational function and training of people.

Senator McCLELLAN. Well, to say the least, while the original contractor with the Government is doing research, and so forth, it might very well be claimed that if he is granted the patent where the Government makes a contribution in the research and development cost, if he is granted a patent, he will exploit it, and therefore he is profiting off of the taxpayers' investment.

But that certainly would not apply to your university. You would be making no profit. You are not in a position to exploit it or to make a profit from it in that way.

Dr. SEEVERS. The university is contributing manpower and know-how and everything that goes along with the development, without any idea of doing anything except continuing to do the same thing.

Senator McCLELLAN. I only bring that out to emphasize that you are impartial, that you are not acting from a selfish motive. No selfish motive could be ascribed to the universities for seeking to do what they think will protect the cooperative working arrangements that exist now, which apparently seem to be satisfactory. Also, under this procedure that you generally follow now, the public, you think, gets the greatest benefit from it.

Dr. SEEVERS. That is my opinion.

Senator McCLELLAN. That is your opinion.

Thank you very much, Doctor.

Dr. SEEVERS. Thank you, sir.

Senator McCLELLAN. Mr. Munns. Will you come around, please, sir?

STATEMENT OF WALTER A. MUNNS, PRESIDENT, SMITH KLINE & FRENCH LABORATORIES, PHILADELPHIA, PA., ACCOMPANIED BY DR. J. KAPP CLARK, VICE PRESIDENT OF RESEARCH AND DEVELOPMENT

Mr. BRENNAN. Mr. Munns, you have a prepared statement. Do you wish to read it or have it printed in the record?

Mr. MUNNS. If you will, please, sir.

Mr. BRENNAN. Have it printed in the record?

Mr. MUNNS. I'll read it, please.

Mr. BRENNAN. Would you identify your associate for the record?

Mr. MUNNS. I have that all in my statement, if I may proceed accordingly.

I am Walter A. Munns; I am president of Smith Kline & French Laboratories of Philadelphia, a manufacturer of prescription drugs. I am accompanied by Dr. J. Kapp Clark, vice president of research and development.

My career with the company started 36 years ago. In 1945 I was named a vice president, became executive vice president in 1956, and in May of 1958 was elected president of the company.

The history of Smith Kline & French Laboratories goes back through 124 years of continuous operation. More than 5,000 people are employed by the company, 3,500 in this country and about 1,500 abroad. We have 30 foreign subsidiaries or branches, and own and operate manufacturing plants in five foreign countries. Our products are marketed throughout the world. With annual sales around $200 million, the company is among the top 10 prescription drug companies in America and has approximately 14,000 shareholders. In 1965, we plan to spend about $23 million for research.

I have requested an opportunity to testify before this subcommittee in order to comment broadly and generally on the impact upon my company of Government patent policy.

I should like to emphasize, however, that although in this testimony I represent the point of view of Smith Kline & French, I am also firmly convinced that I represent the interests of the American people. Our common objective is certainly the health of our Nation, which has already so greatly benefited by the development of the breakthrough drugs that have practically eliminated some diseases and greatly reduced the death rate and length of illness from others. Our objective must be the most rapid possible development of new medicines, and whatever legislation is proposed should in the public interest be geared toward the greatest possible stimulation of medical and drug research.

First of all, I would like to make clear the tremendous gulf there is—in terms of time, research effort, and money—between a new and patentable chemical compound and a safe and effective medicine in a bottle that can be used to treat human beings.

I should like to begin briefly by describing the background of the latest product we introduced, a new diuretic discovered by my company and marketed in 1964. The work on this product is typical of pharmaceutical research and development, whether or not Government funds are involved, and a description of it will, I believe, give you an idea of the great amount of time and money we spend on our R. & D. programs.

Indicated for the treatment of water retention in body tissue from widely varying causes, this product is effective in many patients resistant to other diuretics and, in combination with other diuretics, potentiates their effect. It has the advantage of not causing a loss of potassium from the body, an undesirable characteristic of many other diuretics.

This compound, whose generic name is triamterene, was discovered as part of a program of research we were conducting on diuretic agents, and a patent was applied for in 1959. Though it is impossible to allocate the exact costs, the expense of this patentable invention probably did not exceed $50,000. Then came the major part of the research and development effort, the transformation of the compound triamterene into the medicine we market under the trademark "Dyrenium." This work on Dyrenium took 5½ years and cost over $2 million.

As the table in my prepared statement indicates, our activity from the beginning of animal tests to the decision to test in man required 15 months and cost $350,000; from the beginning of clinical testing to new drug application submission required 18 months and a cost of $735,000; and then, from the time the new drug application was submitted to the time that we received Food and Drug Administration approval to market required 33 months and a cost of a little over a million dollars. The sum total of all this was 5½ years of time, and a little better than $2 million cost.

This was a hazardous speculation. At any time during this process the product might have been shown to have some property that would have made it unsuitable for human administration, and our work and expenses to that date would have gone for nothing. We could never have justified this speculation without the exclusivity provided by a patient.

In the case of Dyrenium, there was, of course, no question of patent protection. We have the patent rights. The cost of the original research and the subsequent development was paid for by Smith Kline & French Laboratories alone.

But many of the important drugs now in use or under current investigaton have been discovered through collaboration between academic scientists and drug companies, and, with proper legislation, this collaboration should become even more productive in the future because of the great expansion in the Government's investment in medical research. Although the subcommittee is undoubtedly familiar with the process of collaborative research in the health field, I would like to amplify certain aspects of it, since it is so different from that in certain other fields where the Government normally makes a research contract with a commercial concern.

What usually happens in the health field is this: The Government makes a research grant to an academic scientist in a nonprofit institution, such as one of our great universities, to investigate a given field. In the course of this investigation, the scientist discovers a new compound, but he does not know what this compound will do to human beings. He may have a hunch that it has medicinal use because of its chemical relationship to known medicinal agents. But he cannot be sure, and the odds against it being a valuable medicine are estimated to be 5,000 to 1. It is rare indeed that the chemist has the biological data about his compound upon which to base a prediction.

The only way in which the medicinal value of his compound can be demonstrated is by exhaustive testing, first in animals, then in humans. For the most part, universities do not have the time and facilities for the required animal testing, nor is this type of testing in keeping with their academic purpose. It is logical, then, that the discoverer of a new compound goes to a drug firm for help since, as the subcommittee knows, industry does have complete facilities and long experience in testing chemicals in animals. For example, in 1964 S.K. & F. used more than 500,000 animals in its testing program. Let me again emphasize that such tests offer the only way in which knowledge can be gained about the therapeutic action of a drug before it is evaluated in man.

Drug testing in animals has today become so complex that new methods of testing are often invented as the investigation proceeds. For

example, in the research on the diuretic project I mentioned, conventional tests had failed to show diuretic activity, and on that basis the compound might have been shelved. In devising ways to test other agents for diuretic activity, however, a new test was developed, and this test revealed that our compound did have diuretic activity.

After it has been determined in animals that a compound has an activity which suggests a medically useful effect in humans, the even greater hurdle of determining its activity, safety, and effectiveness in man must be overcome. Drug companies work closely with hospitals and other medical centers to study drugs in humans, and they have techniques and specialized skills for evaluating the resulting data. This phase of developing a medicinal product, known as clinical testing, involves hundreds of physicians, thousands of patients, and takes at least 2 years to carry out. If the evidence shows that the drug is safe and effective in humans, the final step is to secure marketing approval from the Food and Drug Administration.

Another complication in this process I have been describing is the development of a suitable dosage form, one that will permit the patient's body to absorb and utilize the active ingredient of the drug product. Work on this task begins fairly early in the process and requires the solving of a number of difficult technical problems.

I have emphasized the role of our industry in making a medicine available to the public because I would like the subcommittee members to bear this point in mind as I now discuss the kind of patent policy I believe is needed to stimulate drug research and to bring new medicines to the American people.

First of all, is it not true that the keystone of a sound policy as to Government patents is to lay out a system which will produce the maximum utilization of inventions for the benefit of the public?

With "maximum utilization by the public" as the criterion, certain facts would appear pertinent:

1. Our American patent system is almost universally considered as being one of the most potent factors producing this country's industrial and scientific progress. It is based on the premise that the granting of marketing exclusivity for a given period of time is the best way of bringing new inventions into widespread use.

2. If this reasoning is sound, it is obvious that it should apply to the health field to the same extent that it applies to other fields. A new chemical compound will not help a sick person until it has been made into a medicine, and the whole reason for medical research is to help cure sick people.

3. Any patent legislation or any Government patent policy that discourages collaboration between university scientists and drug companies is likely to slow up the development of new medicines.

As I mentioned earlier, the discovery of new medicines should, in the public interest, more and more involve the collaboration of university scientists and drug companies. For effective collaboration, both the university scientist and the drug company must have incentives, first to invent the compound and then to make the speculative investment required to turn it into a medicine. These incentives have traditionally been provided by our patent system. Indeed, the en-

couragement to invent—to "promote the progress of science"—is the only purpose of the patent system. It seems contradictory to remove this incentive from the health field.

In my opinion, the existing Government patent policy for the health field discriminates against academic-industry collaboration by providing that, if Government money is given to the university scientist, the Government takes the patent rights. With rare exceptions, the university, the university scientist, or the drug firm, which may have spent many hundreds of thousands of dollars for development, do not get any exclusive rights.

I can illustrate the complications that now arise under present patent policy by another example from our own experience. Back in 1959, my company began working with a university scientist who had been studying certain steroids for several years under a Public Health Service grant of $26,000 a year.

We have a program in the field of atherosclerosis and heart disease, and we were determining the effect of compounds on blood cholesterol. This effect was not one of those specifically under investigation by the scientist, nor was it contemplated in the PHS grant. We were able to demonstrate through exhaustive tests in animals that the compound in question lowers the cholesterol level of blood without the side effects which, in the past, have limited the use of other drugs.

We are now at the point where the compound should be given to humans for preliminary evaluation. But to date we have been unable to conclude an agreement that will give us reasonable exclusive rights, even though our investment in development already amounts to approximately $250,000 and may well amount to a couple of million dollars before the compound becomes a medicine for human use. We are continuing to negotiate.

Senator McCLELLAN. Now, as I understand it, this is a case where the Federal Government has made a contribution to your research.

Mr. MUNNS. Not to my company, sir.

Senator McCLELLAN. Well, I mean to the university.

Mr. MUNNS. To the university where the scientist was working.

Senator McCLELLAN. Yes.

Well, you say, "We are continuing to negotiate." Who is trying to negotiate?

Mr. MUNNS. We are trying to negotiate with the university or the Research Corp., the university's patent agent, or HEW, or NIH, as to what kind of exclusivity may be possible under this arrangement.

Senator McCLELLAN. Well, If I understand, this is a case where the Federal Government, the NIH, has made a contribution to your research effort.

Mr. MUNNS. To that of the university.

Senator McCLELLAN. The university. But you are the one that discovered the product.

Mr. MUNNS. Discovered the utility of that compound.

Senator McCLELLAN. The utility of it. What do you mean by the "utility of it"?

Mr. MUNNS. A different utility than was anticipated under the grants given by the NIH.

Senator McCLELLAN. In other words, the grant was given for one purpose, and in pursuing that purpose you made the other discovery.

Mr. MUNNS. The grant was given to the university. The findings of that scientist were published. We became interested in the compounds because we were working with steroids, and we asked whether we could examine those compounds and put them through our screening to see whether they would have some value in the field in which we were interested. That was agreed upon, and then we worked with those compounds and with that scientist to some degree.

Senator McCLELLAN. Now, you have gotten to the point where you think it does have a value?

Mr. MUNNS. We think it does have a medicinal value. We don't know yet.

Senator McCLELLAN. You don't know.

Mr. MUNNS. We know it has a use, but whether it is going to be an acceptable medicine is still quite unknown.

Senator McCLELLAN. Well, it at least gives some promise.

Mr. MUNNS. Yes, sir; it gives some promise.

Senator McCLELLAN. Enough that it would be attractive to you to take the risk of expenditures to explore and develop further and test, and so forth?

Mr. MUNNS. That is correct; yes, sir.

Senator McCLELLAN. Which you say may cost as much as $2 million?

Mr. MUNNS. It could run that much; yes, sir.

Senator McCLELLAN. Now, what position are you in if you do not get some exclusive use of it?

Mr. MUNNS. Well, if there were no exclusivity at all, sir, I don't believe we could afford to run through this whole process of developing a medicine, because then the whole information would be in the public domain, which would permit our competition to move right in at the same level we were, with no expenditures. We have got to recoup.

Senator McCLELLAN. In other words, you might spend a million dollars on it and then find out that it did not have the value you thought, and that would be a loss.

Mr. MUNNS. Yes; that would be down the drain.

Senator McCLELLAN. It would be down the drain.

Mr. MUNNS. Yes, sir.

Senator McCLELLAN. Now, if you spend, say, $2 million on it and found it did have a value, then what is your position? That you should have some protection and some opportunity to recoup that investment, plus a profit?

Mr. MUNNS. Yes, sir.

Senator McCLELLAN. And the only way you can do that is by having an exclusive right as granted by a patent?

Mr. MUNNS. That is correct, sir.

Senator McCLELLAN. Well, now, the argument here is, maybe a license should be given to you for just 2 or 3 years.

Mr. MUNNS. Well, if you will let me finish my statement, I do get into that.

Senator McCLELLAN. Very well. I have heard so much of this already, I can almost anticipate it.

Mr. MUNNS. You know it by heart.

Senator McCLELLAN. I do not really mean to get ahead of you, but these thoughts arise. All right, proceed. Just go on with your statement.

Mr. MUNNS. Very well.

The situation I have just described will increasingly be a problem in the future as more and more Federal money is contributed through grants to hospitals, universities, medical schools, and medical centers. Can drug firms collaborate with these institutions if industry is denied a reasonable equity in resulting discoveries? My own opinion is that drug firms will have to shy away from such collaborative research under existing Government patent policy, as indeed they are already doing.

Senator McCLELLAN. Now, there you conclude that sentence by saying, "as indeed they are already doing." Do you have concrete evidence of that work?

Mr. MUNNS. I think that could be developed, sir. The witness before me laid stress on that, where other drug companies were hesitant——

Senator McCLELLAN. Do you have any personal knowledge of such an instance?

Mr. MUNNS. It is a consideration that we have to think about when we have our own drugs, and we want——

Senator McCLELLAN. In other words, your own case is an instance.

Mr. MUNNS. Yes.

Senator McCLELLAN. The one you have just cited.

Mr. MUNNS. Yes; because if we went to a university or asked a scientist to collaborate with us, one who was under a Government grant, and in that process he found a variable use or a different use for this same substance, under those circumstances that new use patent would revert to the Government.

We in turn, working in our own shop, let us say, might easily have discovered the same thing. We would or we would not, but at least that possibility is always a distinct one, so that it would make us hesitant.

Senator McCLELLAN. All right.

Mr. MUNNS. I therefore urge the subcommittee, in considering legislation, to aim at providing the maximum—not the minimum—incentives for medical discovery to university scientists and to the drug industry. I urge this because I sincerely believe that such a policy is in the national interest, and that it will bring the greatest good to the American people.

A very clear principle is involved. Our patent system stimulates the discovery of new and useful products and processes, and its incentive should not be reduced or denied in the field of health.

I would like to suggest the following principles which, in my opinion, should be considered in determining the form of any new patent legislation involving inventions with Federal support:

1. Where a scientist working in a nonprofit institution and supported by Government funds discovers a new compound that may have medicinal use, the patent rights should belong to his institution, subject to certain Government-retained controls.

2. The nonprofit institution should have the right to negotiate with industry to carry out screening, testing, and development work, and may further negotiate a royalty-bearing license with industry upon such terms as they may agree upon, subject again to Government-retained controls. The license agreement may also define the respective rights of the nonprofit institution and the industrial concern as to new uses and related development and improvements which may result from collaborative work between them.

3. In view of the substantial expenses which must be borne by the industrial concern to develop and test the compound, and considering that the royalties will accrue to the institution and be available for further research, with such award to the individual inventor as the institution deems appropriate, the license to the concern must be attractive enough to invite its participation in this research and development.

We have given considerable thought to specific amendments to S. 1809 and plan to submit them to the subcommitee at the earliest possible date.

That concludes my comments, Mr. Chairman. Thank you for your courtesy.

Senator McCLELLAN. Thank you. Are you prepared to submit the amendments today, or do you wish to submit them later?

Mr. MUNNS. I would like to submit them later, if I may.

Senator McCLELLAN. Very well.

Mr. MUNNS. They have not been—we haven't completely finalized them.

Senator McCLELLAN. I personally appreciate it when those of you who have an interest in this, if you find some way that the bill can be improved, make your suggestion and then prepare the amendments that will carry out your recommendation so that we can better understand exactly what you wanted and what you mean and what the effect of your recommendation would be if adopted.

Mr. MUNNS. Well, you can appreciate that this is a very important piece of legislation that you are considering.

Senator McCLELLAN. That is right.

Mr. MUNNS. And we are working, just as diligently as we can, to send to this committee our proposed or suggested amendments to your bill.

Senator McCLELLAN. Thank you. I was just trying to emphasize that we will welcome such assistance from interested people.

Mr. MUNNS. We will try to get them to you just as quickly as we can, sir.

Senator McCLELLAN. Very well. Thank you very much.

All right, Dr. Zucker, will you come around, please. We are ready to hear you.

STATEMENT OF WILLIAM ZUCKER, PRESIDENT, SOUTHEASTERN PENNSYLVANIA ECONOMIC DEVELOPMENT CORP.

Senator McClellan. Very well, Doctor. You may proceed. You have a prepared statement.

Mr. Zucker. I have, sir.

Mr. Chairman, I am William Zucker, president of the Southeastern Pennsylvania Economic Development Corp., a nonprofit organization created last year with the support of the business and financial community in the 5-county industrial area of which Philadelphia is the center, and which is composed of the counties of Bucks, Chester, Montgomery, and Philadelphia.

I have this prepared statement, which I would like so much to read if I may, and then be available for questions.

One of the concepts on which Spedco—which is what we call our organization—is based is that of encouraging economic development and industrial growth by creating an environment where new ideas in research and development of individual inventors who lack financial resources of their own can be translated into actual industrial production.

The patent incentive is an essential element of this process, and with Federal research and development programs expanding as they are, the potential impact—good or bad—of Federal agency patent policy on science-based, non-Government sectors of the economy cannot be overemphasized.

This is why the organization directed me to make known to your subcommitee, Mr. Chairman, our views on these important issues.

Let me briefly outline for you one key portion of our program which, by the way, is the first of its kind ever undertaken in this country, and which is jointly supported by our own business, financial, and academic communities and by the Federal Government itself through a technical assistance contract with the Commerce Department's Area Redevelopment Administration.

We have set up a new regional development laboratory, where inventors and researchers can obtain space in which to work up and test out their ideas, using our laboratory's specialized equipment and facilities, and having available to them a wide range of technical consulting services.

We designed this laboratory to provide the inventor or researcher with the best possible conditions in which to develop marketable, job-producing, economy-building products and services in the shortest possible time.

We believe it is important to take the individual inventor out of the basement, kitchen, or garage and give him the advantages enjoyed by his counterparts in well-supported industrial and academic laboratories.

Spedco's development laboratory will provide space for 12 "research associates," as we call them, who will pay service fees ranging from

$500 to $2,000 a year, depending on the extent of the R. & D. support that they require. All other costs are underwritten by the sponsoring organizations—ARA during this first year; Spedco and the West Philadelphia Corp.

The latter, parenthetically, is a second nonprofit corporation founded by the University of Pennsylvania, Drexel Institute of Technology, Philadelphia College of Pharmacy and Science and Philadelphia's Presbyterian Hospital to coordinate and stimulate the construction of University City, a 2,000-acre area being developed by private and public capital into a new urban community in West Philadelphia, distinguished by 16 educational and medical institutions. Our development laboratory is in the University City science center complex.

The length of time a Speco research associate will be permitted to occupy space in the laboratory varies with the product or service he is trying to develop and the progress he is making. When an idea has reached the prototype or model stage, the inventor will move out so that others may have access to the laboratory's facilities and opportunities for cross fertilization of ideas.

We already have 4 of the 12 research associates that our laboratory is equipped to house, and discussions are going forward with others.

One is working on electronic devices for fire detection and for burglary detection.

A second is developing a low-temperature (cyrogenic) surgery probe and an instantaneous blood-flow reading device.

Polymer chemistry is the third associate's field, and the fourth is medical information retrieval.

Just before I came down last night, we signed up our fifth one, who is developing an electronic scanning device for the golf swing, so that if it is successful——

Senator McClellan. For what?

Mr. Zucker. For golf swing, sir. So that if it is successful, there will no longer be golf duffers in America. [Laughter.]

Senator McClellan. Say that again.

Mr. Zucker. This man has invented a scanning device hooked up by electronic devices with an IBM program device which examines the person's golf swing, his stance, the weight of the club, the way in which the golfer approaches the ball; and, hopefully, he will develop through this testing device a new way of approaching the ball and swinging the club. It will be sold to golf pros.

Senator McClellan. Is there any stock for sale in that? [Laughter.]

Mr. Zucker. I would like to point out, if I may just proceed, Mr. Chairman, that all of these are new and novel ideas that we are trying to develop.

Now, the Area Development Administration of the Department of Commerce is providing us with $120,000——

Senator McClellan. On this particular thing?

Mr. Zucker. On the entire laboratory, not on this device. No, sir.

We then provide some $45,000 in additional funds. But the patent device and the patent rights belong to the research associate. They

do not belong to the Federal Government, nor do they belong to Spedco, nor do we have any financial rights in the product at all.

But this is one of the first times in which a Government contract was written in which the research associate's patent rights belong to him and do not revert to the Federal Government.

We pioneered in this R. & D. facility because it represents a single approach, a first approach which we hope will be duplicated throughout the country.

We have emphasized the fact that our area, our five-county area, has indeed quite a complex of R. & D. going on, and we have issued just recently this brochure (indicating), which I would like to leave with the chairman, not to put it in the record.

Senator MCCLELLAN. It may be received as an exhibit for reference, appropriately numbered. We have already had a number of exhibits for reference, and this will be appropriately numbered for reference.

(The brochure referred to will be found in the files of the committee.)

Mr. ZUCKER. Thank you, sir.

In it, we have listed a directory of research and development, and we have found that there are more than 425 laboratories employing about 15,000 scientists and engineers and spending more than $500 million a year in R. & D. R. & D. programs span the entire range of science and technology, with the greatest concentration in aerospace, chemicals, electronics, instruments, machinery, materials, development, medicine, and physics.

When it is completed, the $50 million University City Science Center in West Phildelphia and its already functioning Science Institute will be able to make available to government and industry alike—provided equitable Federal patent policies are developed by Congress and enacted—the research talents of a dozen or more universities, technological institutes, and medical centers.

The interdependence of science and technology, the frequent intermingling of research activities, and the participation of the Federal Government to industrial and academic research cannot be better demonstrated than in southeastern Pennsylvania.

As I mentioned, we had prepared this detailed directory of R. & D. organizations, facilities, and capabilities in southeastern Pennsylvania and, where possible, the sources of support for the work conducted in each.

We found that activities in the area's 425 research centers and laboratories included (1) research supported entirely by industrial concerns; (2) programs supported entirely by the U.S. Government under contracts or grants, and (3) also it had programs in which Government projects are going forward side by side, with research being conducted with a company's or university's own funds and with other, nongovernment contract or grant-supported work.

Monitor Systems, at Fort Washington, for example, is a small company with $2.5 million research volume in communications. All its work, at the time of our survey, was for the Government.

General Electric's Missile and Space Division employs 5,500 research personnel in a broad range of disciplines, with 95 percent Government support and 5 percent funded by GE itself.

Kellett Aircraft has a $500,000 research volume; is doing 20 percent of its work for itself, 70 percent for the Government, and the other 10 percent under contract for other industry.

Atlantic Refining, on the other hand, has a research staff of 362, doing 95 percent company work and 5 percent Government work.

Rohm & Haas, a major chemical concern, spends $15 million annually for research, all on its own account.

Intermingling of research and research support is most evident on the university campus. For example, Villanova's research, which runs to $90,000 a year, is supported 10 percent by the university, 75 percent by the Government, and 15 percent by industry.

At Hahnemann Medical College, with a $2.3 million program, the support ratios are: the college 8 percent; Government 80 percent; industry 10 percent; and "other" 2 percent.

Our area's biggest academic research center is the University of Pennsylvania, with its $27.5 million program and 2,000 research people. The Government supports 90 percent of this work, the university 5 percent, and industry the other 5 percent.

The difficulty of devising a Federal patent policy that will preserve all the equities in these varied factual situations has long since become clear to this subcommittee, I am sure.

I appreciate your courtesy and your patience, Mr. Chairman and members of the subcommittee, in permitting me to make these general comments about Spedco and its interest in these issues.

Our testimony on the specific legislative proposals will be directed only to S. 1809, introduced by Senator McClellan, and S. 2326, introduced by Senator Dirksen after this subcommittee held its patent hearings during June and July.

We understand that S. 1809, Mr. Chairman, was intended to write into statutory language the provisions of the late President Kennedy's patent policy memorandum of October 10, 1963, to Federal agencies.

We also understand that Senator Dirksen's bill incorporates the recommendations of the American Bar Association and the American Patent Law Association.

In our view, neither of these bills, as introduced by the chairman or by Senator Dirksen, resolves with equity for all concerned the complex issues of Federal agency patent policy, nor do they sufficiently protect the public interest in the context of the Constitution's mandate to Congress (art. I, sec. 8), "to promote the progress of science and useful arts" by means of a patent system.

By comparatively simple amendments, however, either or both could be adjusted, in our view, appropriately to advance and protect the public interest, safeguard the equities of all concerned, and indeed "promote the progress of science."

Section 3(b)(3), on page 4 of S. 1809, reserves to each contractor an irrevocable, nonexclusive, royalty-free license for the practice of any invention arising from research conducted for a Government agency. However, such license is nontransferable except within affiliated companies or successor companies.

This language is sufficient to protect the rights of the contractor if that contractor is a commercial concern with developmental and marketing resources.

But if the contractor is a university, medical school, or comparable nonbusiness enterprise, the license must be transferable by that enterprise if the provision is to place the academic contractor on equal terms with the commercial contractor.

No academic institution of which I am aware has the capacity to reduce an invention to practice and put it on the market, nor any interest in doing so. The only way it can benefit from this clause is to be able to license a company with resources to develop and market a product, and so receive royalties.

We are sure this discriminatory treatment of academic institutions was an inadvertence.

Section 4(a) of S. 1809 describes situations in which an agency head would be required to take principal or exclusive rights for the Government, with a proviso for waiving such taking by the Government in exceptional circumstances.

The purposes of 4(a)(1) and 4(a)(2) are, we believe, laudable. But because the language of 4(a)(1) is inexact, it would extend far beyond any foreseeable requirement of the public interest.

This is particularly true of the phrase "for commercial use by the general public," which could extend to virtually every kind of product, new or old, conceivable by the mind of man.

As for 4(a)(2), its requirement of Government taking of principal or exclusive rights in fields which directly concern the public health, welfare, or safety could well have exactly the opposite effect of that intended in the Kennedy policy memorandum and in this implementing legislation.

This provision would deny to the fields of health, welfare, and safety the incentives of the patent system which has brought so much progress in every field, including these three crucial fields, since the first patent law was enacted 175 years ago.

We agree that these fields are so important in the lives of every citizen that Government should give every encouragement to rapid advancement. But to take away the patent incentive would be to impede advances, not encourage them.

We believe the American Bar Association and American Patent Law Association have worked out a reasoned approach to this specific problem, which has been incorporated in S. 2326.

Its 4(a)(1) would require a Government taking of rights if—

> the purpose of the contract is to produce one or more end items, the use of which is or will be required by law or governmental regulation in furtherance of the public health or safety, and the invention covers such an end item * * *

This phraseology, we believe, fully protects the public interest in the fields of research and development encompassed by both 4(a)(1) and 4(a)(2) of S. 1809. We suggest that both be deleted from S. 1809 and that 4(a)(1) of S. 2326 be inserted in their stead.

S. 1809, in 4(b), discriminates once more against academic and other nonprofit enterprises. This provision would allow the contractor to retain all rights but a nonexclusive Government license, when the research is for products or methods for use by the Government and the work is in a field where "the contractor has acquired technical competence directly related to an area in which he has an established nongovernmental commercial position * * *."

A nonprofit institution like a university or medical school can qualify for these additional rights on the basis of its existing technical competence, but not if it is required to have an established nongovernmental commercial position.

This discriminatory treatment of our great nonprofit research centers can be corrected by additional language limiting the "commercial position" requirement to commercial contractors.

Additionally, we believe it would be good public policy for the Government to avail itself of the outstanding technical and administrative competence of our universities and our medical and other scientific colleges in the handling, on a public interest basis, of patent rights to inventions made in the course of research conducted by the institutions under Government grants or contracts.

This can be accomplished by incorporating a provision in this legislation directing the agency head to acquire no more than a nonexclusive license for the Government if the contractor (1) is a nonprofit institution, (2) has a patent policy approved by the agency head. The institution would hold and exploit the patent.

This system has been used for many years by the Public Health Service in administration of inventions made in the course of NIH-supported research, as the subcommittee knows.

The provision should, we suggest, contain language requiring the agency head to approve an institution's patent policy if such policy will advance the public purposes of the institution, and specifically allowing approved policies to include appropriate incentive payments, based on a percentage of royalties or other reasonable criteria, to the individual inventor or inventors.

S. 1809 wisely provides authority for Federal agencies to grant exclusive or nonexclusive licenses for the practice of inventions on which the agency holds patents, with or without the payment of royalties, and for as long as the life of the patent, if this is in the public interest. We strongly support this.

On the other hand, S. 2326 in 4(c), while it reserves to the contractor "at least a nonexclusive, royalty-free right to practice the invention * * *," can be construed as requiring the Federal agency head to grant to any citizen of the United States or any citizen-controlled enterprise "an irrevocable, royalty-free nonexclusive license to any patent" held by the United States.

This would seem to be required whether the citizen or citizen-controlled enterprise was a participant in the development or not, and would seemingly prohibit use of the frequently essential tool of exclusive licensing.

In fact, this language can be interpreted as requiring that strangers to the contracts and to the research be favored over contractors who made the invention. They would be accorded "an irrevocable, royalty-free nonexclusive license in any patent" held by the United States, while the contractor would be entitled only to a "nonexclusive, royalty-free right to practice the invention."

This would seem to be required whether the citizen or citizen-controlled enterprise was a participant in the development or not, and would seemingly prohibit use of this frequently essential tool of exclusive licensing.

If this phraseology of S. 2326 is intended merely to reserve to contractors alone a royalty-free nonexclusive license to every patent held by the United States that arises out of the research they contract to perform, it should say so more precisely.

However if this section 4(c) is intended to prohibit exclusive licensing of patents held by the United States under any and all circumstances, and your subcommittee adopts this policy, contractors should at least be placed on a par with strangers to the contracts by being accorded the same irrevocable, royalty-free nonexclusive license in patents held by the United States.

We urge the subcommittee not to bar exclusive licensing of patents held by the United States, because forbidding such a licensing on reasonable terms, to encourage private investment of the sometimes large sums necessary to fully develop an invention to the point of practical application, would not be in the public interest.

In the pharmaceutical and medical sciences, for example, the investment of capital and of human and laboratory resources required to bring what pharmacologists call an "interesting" compound to the point where the physician can prescribe it for his patients often involves years of research and millions of dollars.

If the Government should offer this "interesting" compound to every pharmaceutical house qualified to undertake its development, chances are that none would be willing or able to take the risk.

It is only by reasonable market exclusivity that a pharmaceutical company has a chance of recovering its investment and perhaps realizing a profit.

I would like to make one final point on the granting by Federal agencies of exclusive licenses in practice inventions to which the Government holds title.

In today's intermingling and interdependence of research and development, situations may arise where the Government holds a patent or has principal or exclusive rights even when other sponsors—such as a medical school or university or a publicly supported health organization like the American Cancer Society—or a company have made equal or greater contributions than the Government to the research and to the discovery. Equity demands that in cases of this kind the Federal agency be compelled to recognize the contributions and the rights of the cosponsors of the research.

This can be readily done by adding a new clause in section 8 of S. 1809 that would require the agency head to grant an exclusive, royalty-free license to the contractor and/or other persons associated with the contractor in making the invention if the aggregate financial contributions of these persons is greater than that of the Government. Also, the agency head should be required to grant an exclusive royalty-free license to the contractor and/or his associates in the research if the agency head determines that substantial additional expenditures of nongovernmental funds are needed to bring an invention to the point of practical application and that such exclusive licensing would accelerate final development by the contractor and/or his associates and expedite availability of the end product for public use.

Applications for this kind of exclusive licensing are based on equities derived from work already performed or commitments to perform

developmental work in the future. Applicants should have available to them, we believe, the same kind of administrative hearings and judicial review provided for in sections 5 and 6 of S. 1809, in the event of agency denial of a reasonable period of exclusivity.

Thank you Mr. Chairman and members of the subcommittee, for this opportunity to present the statement to you.

Senator McCLELLAN. Thank you very much, Dr. Zucker. That is a very interesting statement. I appreciate, too, your suggestion about what amendments would be advantageous and beneficial to the proposed legislation.

Mr. ZUCKER. Thank you.

Senator McCLELLAN. Off the record.

(Discussion off the record.)

Senator McCLELLAN. Very well. Our next witness?

Mr. BRENNAN. Mr. Robert F. Conrad.

Senator McCLELLAN. Will you come around, please, Mr. Conrad?

Mr. CONRAD. Yes, sir.

STATEMENT OF ROBERT F. CONRAD, REPRESENTING TEKTRONIX, INC.; ACCOMPANIED BY THE VICE PRESIDENT, WILLIAM WEBBER, AND J. RUSSELL VERBRYCKE III, AN ATTORNEY

Senator McCLELLAN. All right, Mr. Conrad, if you will identify yourself and also your associate, then you may proceed. I see you have a prepared statement.

Mr. CONRAD. Yes, sir; I also wish to make additional comments.

Mr. Chairman, I am Robert F. Conrad, a patent attorney with offices at 815 Connecticut Avenue NW., Washington, D.C. I am a member of the bar of the District of Columbia, and of the American Patent Law Association. My practice is concerned almost exclusively with patent litigation. My appearance is on behalf of Tektronix, Inc., a manufacturer of electronic equipment, including oscilloscopes, which are electronic devices designed for precision measurement.

On my right is Mr. Verbrycke, who is an associate in my office. We also have with us, in the back row, Mr. Webber, who is an officer of the Tektronix, Inc.

Senator McCLELLAN. Very well, you may proceed, Mr. Conrad.

Mr. CONRAD. Our comments will be directed exclusively to section 8 of the bill S. 1809.

We have comments of two kinds about the provisions of section 8. The first is with respect to the technical language of the bill.

It appears to us that under the present language, the purposes which the committee have in mind may not be accomplished; and secondly, we object to some of the philosophy of section 8, particularly that which enables the Government to bring suit on Government-owned patents against citizens of the United States and collect damages.

First, with respect to the technical matters, which I think can be discussed with reference to the first sentence of section 8(b): You will notice that the first sentence of section 8(b) provides that: "Each agency head may grant an exclusive or nonexclusive license for the practice of any invention for which he holds a patent acquired under this act on behalf of the United States."

Now, at the moment, the Government owns somewhat more than 10,000 patents. Those patents are presently existing, and their average remaining life may be in the neighborhood of 8 years.

Senator McCLELLAN. This is the overall total, is it? The aggregate?

Mr. CONRAD. Yes, sir.

Senator McCLELLAN. This is not in just one specific field?

Mr. CONRAD. It is the overall, Your Honor. The last statement I saw was in the neighborhood of 13,000.

Now, of course, section 8(b) obviously is directed to the administration of patents which are owned by the Government. It details the kind of license that may be granted under the act.

The point which we wish to bring to the committee's attention is that the present language of the act would leave completely in limbo the patents presently owned by the U.S. Government, which number well over 10,000.

Senator McCLELLAN. When you say "the act" you mean the bill that I introduced, S. 1809?

Mr. CONRAD. Yes, sir; I meant the bill S. 1809.

Senator McCLELLAN. Yes.

Mr. CONRAD. We assume that it was intended that the provisions of 8(b) apply to Government-owned patents, presently owned as well as those acquired in the future. This appears in the technical amendments which would repeal certain administrative rules with respect to patents now owned by particular departments.

So, if it was the intention of the committee to bring within the ambit of 8(b) the presently owned patents of the Government, which, of course, will represent the real problem over the next several years, then some amendment to the present language will have to be made.

Now, another technical aspect with respect to section 8 is that the sentence which I have read also provides that the agency head may grant an exclusive license. Ordinarily an exclusive license is literally what the word "exclusive" means, and the agency head, under the present language of 8(b), would be entitled to, if not actually required to, grant a license which would even preclude any rights in the Government.

For example, under this section, the agency head might grant an exclusive license. That exclusive licensee might later turn around and insist that the Government pay a royalty on the very patent which had been exclusively licensed by the Government, the development of which had, of course, been fully paid for by the Government.

This result could be avoided simply by saying that the exclusive license which the agency head is entitled to grant shall be subject to the same kind of a reservation which is described in section 3(b)(5) of the bill.

Those are the only two comments we have with regard to the language of the bill.

The provision that we are most concerned with is made in the last two sentences of section 8(a). These sentences read:

> Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.

Now, I think this might be regarded, really, as a rather significant piece of antitrust legislation. What this provision represents is a departure from historic Government patent policy. Except for one single recent instance, the Government has never brought suit against any of its citizens for infringement of Government-owned patents. This language which I have read would seem to authorize such suits.

Now, we know that suits on Government-owned patents could be—and according to the present policy of the Department of Justice would me—used to actually regulate competition in an industry, and suits on such patents could be usd to regulate competition within industry, even thought that industry or that particular company in the industry was not involved at the moment in anything that was in violation of present antitrust law.

In other words, this provision would give the Department of Justice a new and additional tool with which to regulate competition in any given industry.

The regulation, of course, would be achieved by filing an infringement action against a particular company, and not against others in the industry, with the idea that it would saddle onto that particular company the requirement to pay a royalty which its competitors would not be paying.

It would, of course, undertake to do this only when it thought that adding such a royalty to the costs of one company would result in equalizing the competitive situation in that company's industry.

Now, this is not a speculation on my part. This is the position which the Department of Justice has actually taken in a case which is now pending in the U.S. Court of Claims.

Another aspect of giving the Government the right to sue on its patents is that it really sets up a very unfair contest. For example, there is a very clear Supreme Court law on the proposition that the Government is not subject to any statute of limitations.

Now, with respect to authorizing the Government to bring suits on its patents against its citizens, that rule would have this effect: The Government could today file suit in a U.S. district court and ask for damages for infringement of a Government-owned patent which, say, might have expired as many as 30 years ago.

It could, for example, under the provisions of this section authorizing infringement actions, go back and sue, for example, the electronic companies such as Westinghouse, RCA, and General Electric, for infringement of Government-owned patents which occurred during the last war.

The fact that it has delayed suing for so long a time has led these companies, and perhaps also its policy of not suing on any of its patents for so long a time, into the reasonable belief that it would never sue on them, could not be raised as a defense in any such action, because another firmly established rule of law is that an estoppel or laches cannot be urged against the Government.

Consequently, we would suggest some change in language in section 8 which would put the onus of suing for infringement of any Government-owned patents on the exclusive licensee. This would then set up the usual situation one faces in court in a patent litigation case. In connection with a free, nonexclusive license, of course, the Government

couldn't show any damages, even if it did sue for infringement, so it is unlikely that such actions would be brought.

In connection with a royalty bearing nonexclusive license, a complaining licensee might be authorized to bring the suit.

But, in any event, it seemed to us that this provision, section 8, should be amended in some way that takes the Government out as a litigant in patent cases involving Government-owned patents on which infringement suits are brought, simply to avoid the inequities which would follow from the Government participating as a plaintiff.

Now, one other comment we have about section (b) is that it provides that licenses such as are authorized by portions of the provision should be granted with or without the payment of royalty.

Now, it seems that the suggestion that the Government might in some cases want to collect a royalty was simply based on the thought that it would be a sound business practice to do so, it would be prudent as a business matter to collect a royalty where the Government could collect a royalty practically.

We think this overlooks a rather basic consideration. Of course, the Government should follow prudent business practices wherever it can, but we think that such practices have to give way where they conflict with some basic governmental principle such as a provision, for example, in the Constitution.

Now, the patent provision in the U.S. Constitution has, of course, been commented on a great deal by the courts, and over a long period of time the courts have analyzed its purpose as being to increase the storehouse of knowledge which is freely available for all to use. The particular way in which the constitutional provision is written seems to require this interpretation.

Now, of course, when the Government charges a royalty for use of patented knowledge, it is to that extent discouraging the use of that knowledge, and it certainly is not increasing the storehouse of knowledge which is freely available for all to use. To that extent, where it charges a royalty, it is taking a position which seems to us to be inconsistent with the purposes of the constitutional provision.

Also, it is said that the reason for providing for the issuance of exclusive licenses is to encourage the use of these ideas which might otherwise die on the shelf. That, of course, is a laudatory purpose. But consistently with the purpose of the Constitution, it could be even still furthered by omitting to charge a royalty for the exclusive license. That would be, of course, an even further inducement to exclusive licensees to make a success of their ventures with the Government.

Now, in connection with this purpose of encouraging industry to develop, make things practical which otherwise would remain simply as patents on the shelf, gathering dust, I would like to point out that the provision which enables the Government to bring suit on Government-owned patents, under the present policy of the Department of Justice, thwarts this objective.

You might be interested in the case of Tektronix. Tektronix started out not many years ago on a capital of about $20,000, I believe. They were in competition in the oscilloscope business with RCA, Westinghouse, Dumont, and a number of other very large companies, but they offered a better product at a lower price, and the public rewarded them

by buying their products, and they are now a very, very substantial company.

They made the developments at their own expense. These developments, for the purposes of this discussion, can be regarded as improvements on two Government-owned patents which were in fact gathering dust on the shelf until Tektronix improved them and made them practical and embodied them in a commercially useful instrument.

Now, what was the accolade which this company gathered as a result of making this development of the patented Government idea which was moldering away on the shelf? They were rewarded as follows: They were the first company in the history of this country that was sued for infringement of a Government-owned patent. The Government procured their competitors to manufacture Chinese copies of the instrument which the company had developed at its own expense.

Now the Government is taking the position that if Tektronix wishes to use these Government-owned patents, then it must pay damages—that was its first position. It then altered its position to say, "Well, at least you must give to the Government and your competitors, insofar as Government use is concerned, rights under the developments which you made."

We think this is manifestly unfair.

Senator McClellan. How much did you spend on the development?

Mr. Conrad. Sir?

Senator McClellan. How much did you spend on the development of the product?

Mr. Conrad. Well, I don't have the exact figures, Senator, but I could say very safely that it was in the hundreds of thousands of dollars and took place over quite a long period of time.

Now, the provisions of the bill, rather than discouraging this kind of actual retribution against one who develops a Government idea, makes it possible and actually confirms the position which the Department of Justice has recently taken on this.

The Department of Justice has taken a position that it needs no legislation in order to sue on Government-owned patents. But whenever it thinks it is in the public interest to do so, it will bring suit; this, despite the fact that there is no statute authorizing such action; this, despite the fact that there are no standards set out as to what shall govern this determination of public interest, nor who shall make it, and despite the fact that there are no regulations on that.

They also take the position that once they make this determination, it is not subject to review by any court. Well, we think that suit on Government patents is properly a matter that should be resolved by Congress, if in fact any branch of the Government has power to authorize such suits in view of the purpose of the patent provision of the Constitution.

Mr. Chairman, we have prepared a supplement to our prepared statement, in which we make suggested amendments to section 8.

Senator McClellan. Very well. Let it be filed and put in the record, along with your prepared statement.

Mr. Conrad. We think it will continue to carry out the objectives the committee had in mind in writing section 8 and, at the same time, avoid some of these matters which we regard as problems.

Senator McCLELLAN. All right, sir. Do you have anything further?

Mr. CONRAD. No, your Honor.

Senator McCLELLAN. As I said, your statement and the supplement will be inserted in the record.

(The prepared statement of Mr. Conrad together with the supplement referred to follow:)

STATEMENT OF ROBERT F. CONRAD ON BEHALF OF TEKTRONIX, INC.

Mr. Chairman and members of the committee, I am Robert F. Conrad, a patent attorney with offices at 815 Connecticut Avenue NW., Washington, D.C. I am a member of the Bar of the District of Columbia, and of the American Patent Law Association. My practice is concerned almost exclusively with patent litigation. My appearance is on behalf of Tektronix, Inc., a manufacturer of oscilloscopes, which are electronic devices designed for precision measurement.

While we have an overall interest in Senator McClellan's bill, we are primarily concerned with a portion of section 8(a) and with certain of the licensing provisions which would involve the use of that section. The particular part of section 8(a) which we wish to discuss consists of the last two sentences of that subsection which extend from line 23 on page 14 to line 2 on page 15, which read as follows:

"Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose."

This language appears to give congressional sanction to an administrative concept which has recently resulted in a complete reversal in the Department of Justice of a patent policy which has been recognized by both Congress and the executive departments since World War I. Specifically it would authorize the U.S. Government to sue its citizens for the infringement of Government-owned patents.

It is our belief that this committee has not been fully advised how section 8, if enacted, will be administered by the executive departments. Tektronix, Inc., is currently engaged in patent litigation with the United States in the Court of Claims. In this action the Government is attempting, through a patent infringement counterclaim instigated by the Department of Justice, to accomplish the following results:

(a) To extend the antitrust authority of the Department of Justice beyond its present statutory limits.

(b) To control competition within a particular industry, by using Government-owned patents as a means for prosecuting acts which are not violative of the antitrust or any other laws.

It also appears that section 8 involves complications of basic law which also have not been presented to this committee:

First, a serious question of constitutional law is involved. The obvious purpose of article 1, section 8 is to promote the useful arts by enlarging the storehouse of knowledge concerning them to which the public has free and unrestricted access. Any action which the Government might take to prevent the free use of knowledge concerning the useful arts through enforcement of a Government-owned patent thwarts the purpose of this constitutional provision. Therefore, a suit upon a Government-owned patent necessarily wrongfully delays fulfillment of the primary purpose of article 1, section 8.

Second, the enactment of section 8 of the bill would create an injustice by placing the Government in a legal position superior to that of the private patent owner. For example, the Government as a sovereign would have the following unfair advantages in patent litigation:

(a) *Statute of limitations.*—The private owner of patents as plaintiff may not bring an action for any infringement which occurred more than 6 years prior to his action by virtue of 35 U.S.C. 286. The U.S. Government on the other hand has long been held by the Supreme Court not to be prevented by a statute of limitations from asserting rights vested in the Government as a sovereign power. *United States* v. *Nashville, Chattanooga, and St. Louis R.R., etc.*, 118 U.S. 120, is typical of many such decisions.

(b) *Laches.*—The United States as plaintiff, unlike a private company, is not barred by the laches of its officials, however gross, from bringing a suit as a

sovereign government to enforce a public right or to assert a public interest. *United States* v. *Insley*, 130 U.S. 263.

(c) *Declaratory judgment actions.*—Where one is accused of infringing a privately owned patent he may bring a declaratory judgment action to test the validity of that patent. The United States, however, cannot be sued under the Declaratory Judgment Act, 28 U.S.C. 2201, even though it may threaten to enforce its patents against persons accused of infringement. The United States can be sued only to the extent that it has waived its sovereign immunity, and it has not consented to be sued under this statute.

(d) *Patent misuse.*—The courts in a long series of cases have refused to allow the patent owner to enforce his patent, even though it be of unquestioned validity, where he has been guilty of some one of the many practices which constitute "misuse of patents." Again the unique position of the United States as sovereign would make it impossible to assert these defenses should the Government institute an action for patent infringement.

(e) *Right of licensee to test validity.*—In a number of decisions the Supreme Court has stated that it is in the public interest to insure a licensee the opportunity to free itself from licensing restrictions which are imposed under a patent which may be invalid. It has recognized that the licensee must have access to the courts to test the validity of the patent where the restrictive conditions, but for the patent, would be contrary to the Sherman and Clayton Acts. *Katzinger Co.* v. *Chicago Metallic Mfg. Co.* (329 U.S. 394), *Macgregor* v. *Westinghouse Elect. and Mfg. Co.* (329 U.S. 402). Where the Government is licensor, the licensee is deprived of this means of litigating the patent under this body of case law, and the United States has still another unfair advantage when compared to private owners of patents.

CONCLUSIONS

One does not have the same rights against the Government as the party asserting the proprietary rights under a patent as one does against a private patent holder. The unfairness of creating a litigant in the unique position of a sovereign becomes even more serious when it is considered that the Government is one of the world's largest owners of patents, and that these patents cover inventions in virtually every technology. Additionally and aside from the constitutional and other legal questions, it is inappropriate for the Government with its limitless resources of public funds and vast legal staff, to set itself up in the patent business. The average litigant is simply not able to exercise his normal legal rights where the Government is a party litigant.

Therefore, the last two sentences of section 8(a) should be deleted. The United States has all the authority it needs to carry out its historical functions of obtaining and preserving patent rights. These include:

(*a*) Authority to acquire title to inventions financed with public funds;

(*b*) Authority to assert invalidity of patents defensively in the Court of Claims on which infringement claims are filed against the Government; and

(*c*) Authority to participate in interference proceedings in the Patent Office.

In order to eliminate any need for the portion of section 8(a) to which objection is made, section 8(b) should be amended to eliminate the authority of the agency head to issue any license which is not nonexclusive, royalty-free, and equally available to all applicants.

Should the committee, however, feel that in exceptional circumstances the public interest requires the granting of an exclusive license, such license should be royalty-free, and should provide that the licensee would be solely responsible for the prosecution of infringers and defense of the patent to the same extent as if it were the owner as well as the licensee. The bill should also contain a provision which would prevent any participation whatsoever in any such litigation by the United States as either plaintiff or defendant.

If thus amended, the more serious objections to the bill would be eliminated. The Government's traditional role in patent litigation would not be enlarged, and it would continue to participate as defendant in the Court of Claims under section 1498 of title 28.

Having concluded my comments as to the bill itself, I will briefly highlight the case of *Tektronix, Inc.* v. *The United States*, so that the committee will be completely aware of the manner in which the Department of Justice will exercise the authority which section 8 would confer.

In 1961 Tektronix brought a patent infringement action in the Court of Claims against the United States. In patent parlance it took the position that the United States had awarded a series of contracts to Tektronix's competitors to make "Chinese copies" of Tektronix's patented oscilloscope. This was an ordinary infringement suit, which became unique when 2 years later the Government filed a counterclaim against Tektronix. This is the first time in history that the United States has asserted a patent against one of its citizens, and has thus questioned the right of all people to make free use of its patents. From its briefs and oral arguments the Government's position is as follows:

(*a*) Tektronix patented oscilloscopes employ two patented electric circuits the ownership of which was assigned by the inventors to the Departments of the Army and Navy, respectively. These two Government patents as well as those of Tektronix are embodied in the Tektronix instrument.

(*b*) Tektronix made use of the two Government-owned patents without having first applied for a license from the Army and the Navy.

(*c*) Tektronix must now agree to a cross-license under which the Government and its contractors will be licensed retroactively to use the patents of Tektronix in exchange for the right of Tektronix to use the two Government patents.

(*d*) There is no statutory authority for the compulsory cross-licensing which the Department of Justice is attempting to force upon Tektronix, but it has the inherent authority to determine where the public interests lie and to use its patents to enforce such determinations.

(*e*) It is "in the public interest" for the Department of Justice to promote competition in the oscilloscope industry and to put Tektronix "in the same position as other members of the oscilloscope industry" and to "equalize opportunities" in the competition for Government purchases of oscilloscopes.

The Department of Justice states that it has the inherent authority to make the determinations involved and to enforce them even though the action was taken without the knowledge of either the Department of the Army or the Navy, the Departments to which these two patents are assigned. The Justice Department states that it needs no authority from Congress to make and enforce these "public interest determinations." It even goes so far as to contend that these decisions are beyond the reach of the courts in that they are the exercise of administrative discretion.

The main theme of President Kennedy's directive on Government patent policy and the announced objective of this committee is to foster the commercial application of Government-owned inventions. It should be assumed for purposes of this discussion that Tektronix did make use of the Government-owned patents in producing its new oscilloscopes. No one contests the fact that Tektronix did introduce a new instrument which is cheaper and far superior to any oscilloscope which had been available previously. It is also admitted that the new instruments were the result of the expenditure of a great deal of time and money, all of which was borne by Tektronix. Nevertheless the United States is now suing Tektronix for developing two Government-owned patents to the point of great commercial utility because it did not first obtain a license to do so. Obviously the patent policy currently being followed by the Department of Justice is completely at odds with the objectives of this committee. There can be no clearer indication of the manner in which the broad delegation of authority contained in section 8 would be administered, if this section should be enacted.

I fully concur in the recommendations of the American Bar Association, the American Patent Law Association, the National Association of Manufacturers, the National Small Business Association, and the many others who appeared before this committee and recommended against the enactment of so much of section 8 as authorizes the U.S. Government to initiate patent litigation against the citizens of this country.

The opportunity to present these views is greatly appreciated, and it is hoped that the information which has been furnished will focus attention upon an area which requires careful study by this committee.

SUPPLEMENT TO STATEMENT OF ROBERT F. CONRAD ON BEHALF OF TEKTRONIX, INC.,

SUGGESTED AMENDMENTS TO SECTIONS 8 AND 3 OF S. 1809

SEC. 8. (a) Whenever an agency head has taken title to any invention by declaration of acquiring which has become final or by authority of any other provision of this Act, *or otherwise has heretofore acquired ownership of an invention,* and he has reason to believe that such invention is patentable, he may make application to the Commissioner of Patents for the issuance of a patent therefor to such agency head on behalf of the United States. If the Commissioner determines that such invention is patentable, he shall issue to such agency head on behalf of the United States a patent therefor. [Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.]

(b) Each agency head [may] *shall offer to* grant an exclusive *license subject to a reservation to the United States the same as that set forth in Section 3(b)* (2) or non-exclusive licenses for the practice of any invention for which he holds a patent *heretofore or hereafter* acquired [under this Act] on behalf of the United States. Any such *exclusive* license shall *convey the sole right to sue for infringement and shall* be granted *royalty free to a citizen of the United States* under such *additional* terms and conditions as the agency head shall determine to be in the public interest. Any such *non-exclusive license shall be irrevocable, for the life of the patent, and royalty free and shall* be granted [for the effective period of the patent or for a more limited period of time, and may be granted with or without the payment of royalty to the United States] *to any United States citizen who applies under such additional uniform terms and conditions as the agency head shall determine to be in the public interest.*

To make the remaining provisions of the bill consistent with the changes suggested above with respect to section 8, the following change should be made in section 3(b)(5):

Page 5, line 2, following "licenses" add "such as provided for in section 8(b)".

Page 5, lines 3 and 4, cancel "upon such reasonable terms and conditions as the agency may prescribe".

Senator MCCLELLAN. I believe there is one witness remaining on the list of those scheduled for this morning, Dean Nobles. Will you come around, please.

STATEMENT OF DEAN W. LEWIS NOBLES, GRADUATE SCHOOL, UNIVERSITY OF MISSISSIPPI

Senator MCCLELLAN. I note that you have quite a lengthy statement. Are you willing to have it printed in the record in full, and then just comment on it?

Mr. NOBLES. Yes, Mr. Chairman, I would like to request it, please.

Senator MCCLELLAN. Just glancing at your statement, I would think it will take 2 or 3 hours to read it.

Mr. NOBLES. Yes.

Senator MCCLELLAN. So let it be printed in the record, and you may highlight it now.

Mr. NOBLES. Yes.

Senator MCCLELLAN. Off the record.

(Discussion off the record.)

Senator MCCLELLAN. Back on the record.

(The prepared statement of Dean Nobles follows:)

STATEMENT OF DEAN W. LEWIS NOBLES

Mr. Chairman and distinguished members of the Subcommittee on Patents, Trademarks, and Copyrights, of the Senate Judiciary Committee, my name is Lewis Nobles and I appear before you today as an individual vitally interested

in the matters now pending before this subcommittee as they relate to discoveries and inventions which may be forthcoming from our scientific and technological community and the relationship of such discoveries and inventions as they pertain to the welfare of the people of the United States.

I am a professor of pharmacy and pharmaceutical chemistry at the University of Mississippi, where I also serve as dean of the graduate school. I hold membership in the American Chemical Society, the American Pharmaceutical Association, and the New York Academy of Sciences. I am a fellow of the American Association for the Advancement of Science. I am the author or coauthor of some 60 scientific papers in the field of pharmacy and pharmaceutical chemistry. I have no connection with any industrial organization interested in the pending legislation. For the information of the committee, I am enclosing as appendix I a curriculum vitae to give more detailed information relative to my education and experience. I have no connection with any industrial organization interested in the pending legislation.

As I understand it, you have four bills before your committee for consideration:

S. 1899, introduced by Senator Long;
S. 1809, introduced by Senator McClellan;
S. 789, introduced by Senator Saltonstall; and
S. 2326, introduced by Senator Dirksen.

Since I am not a lawyer by profession, I am not acquainted with the possible legal ramifications of many aspects of these individual bills; I do wish, however, to address myself to certain aspects of what I believe to be a desirable end result in patent legislation so as to insure its maximum usefulness to all those concerned with this problem.

I have been quite interested in this area as it relates to matters concerning health, since this is my particular area of greatest concern; I do not believe, however, that we should be deluded into compartmentalizing this problem. It is broad in scope and demands the kind of serious, earnest consideration that this subcommittee is giving the matter.

In the specific area of health-related research, there appear to me to be many rather specific types of circumstances which should be recognized insofar as academic institutions are concerned; I should like to address myself to four of them:

1. Those circumstances in which private industry or the institution provide total support for the project and all ancillary enterprises; I believe that the case here is rather clear and all would agree that the patent rights should be negotiated between industry and the university or reserved exclusively to the university in the latter case. (This type of instance would be rare, indeed, if not nonexistent, but the case needs to be recognized, anyway, in my opinion.)

2. The case in which the Government enters into a contract for a specific purpose—the creation of a new drug, poison antidote, medical device or instrumentation—and pays the total cost, including physical facilities, personnel, equipment, supplies and all such related items. This is a relatively new concept in American life. There is no question in my mind that programs largely supported by Government funds must be consistent with the public good and the political philosophy of our country. Health is a special area which affects every person in contrast to other segments of our economy. We cannot argue that the Government does not have a lien on discoveries made with Government funds. The question is how to motivate development of observations and discoveries made in these instances in light of the enormous effort and dollars needed to transform them into useful products. How can this be done and still be consistent with free enterprise system?

3. The cases in which there is joint support of the effort, either by the Government, industry and the university, or any other combinations thereof. I am using the term "support" here in the context of sponsorship of research, not as a distinctly mission-oriented operation to "produce a better mousetrap by use of procedures a through d."

4. Among the areas that require clarification is the disposition of rights stemming from nonfederally financed research involving cooperative programs between industry-sponsored grantees and industry sponsors, where either the personnel or the academic institution have benefited from Federal funds for prior or concurrent federally financed projects or facilities. Those contacted in Government circles do not feel that it is even necessary to spell out the disposition of rights in these situations. Yet HEW persists in holding up decisions in this area, even where, for example, the only contact with Government funds has been

the use of a centrifuge or a beaker paid for by the Government in a prior federally financed project.

It is in these last two instances in which we find very little black and white but a great deal of gray area; and I believe that general agreement could be reached that it is in this area in which we find the greatest difficulty of resolution.

I believe that the crux of this problem was summed up very well in a draft of a letter to me last year by Senator McClellan in response to a letter I had written Senator Eastland in regard to this matter:

"The issue of Government patent policy has for a long time caused serious controversy, and perhaps the most difficult phase of this question is the one which you have raised concerning inventions which relate to public health or safety. As I am sure you appreciate, there is considerable sentiment that when an invention effecting public health is produced under a Government contract or grant, the patent rights covering such invention should reside in the Government or that the invention should be freely and fully available to the public. For my part, I fully understand the reluctance of industry to expend funds in the necessary further development of an invention if they are not to enjoy some type of exclusive rights."

The need to arrive at some basis for the equitable measurements of rights was not so great in health research until Federal support reached the extent that the great majority of qualified investigators in every field began to receive some of their support from one or more Federal agencies and virtually every nonprofit research center was similarly involved. Nonetheless, wisdom in the drafting and application of Federal agencies' patent policies has always been of great importance to the scientific community. But in the last decade the growth of Federal programs for conduct and support of research and development in industry and on the campus has been so staggering that the effects of Federal policy are felt today in virtually every laboratory in every community in this country.

If the equities cannot be reasonably defined and rights judiciously assigned, the facilities of the pharmaceutical industry—in certain areas—may well be cut off, at least almost entirely, from the academic investigator and from those in scientific operations within the Government itself. This can only result in harm to all three.

Just as an example, 10 years ago the total budget of the National Institutes of Health for its own research and for grants to medical scientists throughout the United State swas $183 million. This year the overall NIH budget for research and research training will exceed $1 billion.

Ten years ago, perhaps 1 out of 10 of the biochemists and other medical scientists in university research was receiving Federal funds for the support of his projects.

Today, the great majority of competent scientists who can obtain the support of their universities or medical schools in grant applications to the NIH or some other Federal agency are reasonably certain to receive some measure of support for their research proposals in a reasonable percentage of the cases.

With Federal money thus reaching into every laboratory where competent work is being conducted, the impact of Federal patent policy has been staggering.

As Federal programs continue to expand, it will be impossible for any business or nonprofit research organization to work in collaboration with an academic scientist without finding that many of these same scientists are collaborating in Federal Government programs.

The proliferation of Government research and development activity demands that Federal patent policies be developed to assign equitably rights of all of the interests engaged in scientific research whether they be Federal agencies, universities or medical schools, or private business enterprises.

The need for careful resolution of this problem was beginning to emerge a decade ago. It was not, however, as urgent at that time because nongovernment interests were usually able to cooperate with scientists who were not associated with Federal programs and so avoid involvement with Federal patent problems if that was a necessary factor in the advancement of the research underway.

Before and immediately after World War II many graduate students in the sciences studying for advanced degrees were supported by grants from chemical or pharmaceutical companies, from their universities, or from educational and professional societies or publicly supported health organizations like the American Heart Association or the American Cancer Society.

The grants from pharmaceutical and chemical companies were usually outright gifts to support the student with little or no supervision by the granting company of the research being conducted by the student.

Most often the academic scientist had no idea whether his new chemical had any physiological or therapeutic activity until it was subjected to a battery of screening tests by the granting chemical or pharmaceutical company. Results of the screening were customarily reported back to the academician, who would then synthesize other, hopefully more active, compounds on the basis of the test data.

This collaboration between academic and industrial science advanced the competence of the individual student or professor and also contributed to the general advancement of knowledge, for the test data supplied by the company were also frequently published in the scientific literature that is studied by the entire pharmaceutical-chemical profession.

There usually was no formal contract between the pharmaceutical company and the university. It was understood, however, that the chemicals synthesized in the university laboratory would usually be screened by the granting company for possible therapeutic activity.

Only if the compound appeared to have possibilities as a drug in the treatment of some disease would a specific agreement be negotiated between the granting company and university administrators.

Quite often, chemicals prepared by academic scientists under grants from nonindustrial sources were also screened by pharmaceutical companies as a service to a university.

The tremendous expansion of grant funds available from the U.S. Public Health Service (NIH) has been accompanied, as is quite proper where public funds are being disbursed, by a tighter administration of Public Health Service grants and the development of procedures designed to insure that the Public Health Service's traditional public dedication policies are carried out.

As part of the regular procedure, recipients of Public Health Service (NIH) grants are required to submit reports on inventions they develop. They must agree, in essence, when they accept the grants, that the patent rights, if any, will be disposed of by the Surgeon General of the Public Health Service.

If a grantee synthesized an interesting chemical compound or a series of such compounds and wishes to have them screened by a pharmaceutical house, he is required to notify the Public Health Service before entering into any screening arrangement. The pharmaceutical house then is required to sign an agreement relinquishing any patent rights in the test area involved before it is permitted to undertake the screening work. A copy of such an agreement is inserted later in this statement.

A most serious result of this restrictive Federal patent policy, at a time when expansion of Federal research programs has put Federal money into a great many academic laboratories is that many new chemicals are not being tested at all or are not being fully evaluated because drug companies are not able to undertake the work under conditions required by the patent policies of the Public Health Service and its parent agency, the Department of Health, Education, and Welfare.

Why is this taking place?

A pharmaceutical house, which must make a return on any investment in order to survive in this country's competitive economic system, cannot afford to invest the great numbers of dollars required for comprehensive pharmaceutical screening and development without some assurance that it will have a chance of getting its money back and perhaps making some fair profit on its endeavor.

A related consideration is that even if a company were in a position to undertake a screening project for an academic scientist without regard to financial loss, it would be compounding its investment in this nonprofit kind of work because of the fact that it would have to divert its laboratory facilities and its scientific and administrative manpower from its own independent research, thereby losing an opportunity to make some useful invention on its own.

In addition, by incorporating research with some Government-owned compound in laboratories where work of its own is going on, the company takes the risk of having questions raised about possible Government rights to the projects it is conducting in the laboratory at its own expense.

I know that some have written (Science, Jan. 8, 1965, p. 134) that the asserted breakdown in industry-university relations seems remote since it is reported that the industry "appears to" (I have quoted these two words because they are key ones, in my opinion) have spent over $2 million more in R. & D. experiments at academic institutions, medical schools, and related institutions in 1964 than in 1963. These figures are probably true, but they overlook at least

two important aspects of this problem and thus "appear to" tell a side of the story that is not correct, in my opinion:

1. From 1959 to 1964 the number of new chemicals introduced into the prescription market declined from 63 to 17; this despite an increase in expenditures by the industry for research from about 200 million to 300 million. This simply tells me that costs in R. & D. have risen along with the costs of most other items.

2. Much of the research sponsored by industry in academic institutions does not involve a product or idea that is patentable; it involves basic research in human physiology, pharmacology, and biochemistry, to mention only a few. This has come about because of the realization of the tremendous importance of concepts developed here and the implications implicit in them for new drug design while not relating to any specific new drug.

The average academic chemist has extremely limited facilities for testing new chemical compounds prepared by himself or by his advanced students.

Some universities have test facilities in certain specific areas of interest.

Some Government institutions also have limited test facilities.

A few commercial laboratories have been organized to conduct tests of new chemicals with the standard animal screens.

But such facilities, even in combination, are not adequate to handle the testing of the large numbers of compounds now being synthesized in university laboratories. Even where test facilities are available in the nonindustrial sector, many of the more sophisticated screening methods are not in use. For instance, I am told that it is comparatively simple to run a chemical compound through a preliminary screen for antibacterial activity, but it is far more complicated to do screening for neurological and antiviral activity.

Another paradox arises here, in view of the fact that one of the Federal Government's most active and promising research and development programs today is its search, both in its own laboratories and in grant or contract-supported laboratories, for antiviral agents.

At this point, I should like to make specific reference to some of my own personal experiences along this line:

1. One area in which we are quite interested in our own laboratories has been that of the synthesis of possible antiviral agents. Prior to the procedure of NIH which substituted a patent agreement for clause 4(a) on the face of the sheet of the application for research grant, we had received agreement from one of the major pharmaceutical houses to test compounds synthesized under the terms of a grant from NIH for the synthesis of heterocyclic compounds as possible antiviral agents. Following the implementation of this policy (between November of 1961 and the spring of 1962) the pharmaceutical house was placed in the position of having to indicate that they could not sign the new patent agreement, since they were concerned over the scope of its text, which is as follows:

"DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

"Public Health Service

"National Institutes of Health

"Bethesda 14, Md.

"PATENT AGREEMENT

"(substitute for clause 4(a) on the face sheet of Application for Research Grant E-4701)

"Institution:
"Investigator(s):
"Title of Research Proposal:

"The following amended patent agreement is accepted by _____ _____ and becomes a part of the official application for Public Health Service support, identified as _____:

" 'if any invention arises or is developed in the course of the work aided by the grant, the undersigned will refer to the Surgeon General for determination as to whether patent protection shall be sought and how the rights in the invention, including rights under any patent issued thereon, shall be disposed of and administered in order to protect the public interest.'

"In connection with the compounds to be synthesized and/or developed under the subject grant, which are submitted to a pharmaceutical company for screening purposes, the grantee and the pharmaceutical company hereby agree to the following conditions:

"1. The pharmaceutical company shall not make disclosures of the results of testing for a period of 12 months, except with the consent of all parties concerned.

"2. The pharmaceutical company shall report the results of testing promptly to the investigator and will furnish to him, for use by the PHS in connection with any application for patent which the PHS may file, the information demonstrating any utility or new use of the compound.

"3. The pharmaceutical company shall be permitted to obtain patent rights to new uses of the compounds developed at its own expense, except where the grantee contributed or participated in the conception or reduction to practice of such new use, or where such new use patent would hamper, impede, or infringe on the intended use of the invention covered by the product application, or where such new use is within the field of research work supported by the grant.

"4. There shall be reserved to the Government under any new use patent obtained by the pharmaceutical company a nonexclusive, irrevocable, royalty-free license to the Government, with power to sublicense for all Governmental purposes."

"(Accepted) _____ "(Signed) _____
(Pharmaceutical company) (Principal investigator or project director)

"(Title) _____

"(Date) _____ "(Accepted) _____
(Institution official responsible for patent matters)

"(Title) _____

"(Date) _____"

As you can readily observe from this agreement, any pharmaceutical company that would have agreed to it would have been donating its services without hope of compensation, based particularly on item No. 3 above.

In another area, we were preparing compounds for possible use in the general field of mental health; arrangements through NIH were possible for the screening of only four compounds prepared during the course of this work. In this connection, I received a document summarizing the results obtained in connection with the screening of these compounds; this is a document of some 55 pages on only three compounds. The result of this are summarized in a paper recently published in the Journal of Pharmaceutical Sciences; copies of this paper are attached as appendix II to this statement. There are several dozen other compounds in our laboratories now awaiting such testing, but, thus far, we have been unable to get them tested. As an indication of the difficulty in this area, the summary statement of one of the compounds submitted indicated that it demonstrated certain CNS depressant effects in mice, indicating that it might well be considered as a tranquilizing agent for further studies. Until the present policy situation is clarified, I should like to ask the committee: Where is this further study to be done? At a pharmaceutical company which can hope to gain nothing from such studies? This does not appear likely to me.

Perhaps typical of the type of problem noted by many in this field is that cited in appendix 4 of the Woolridge Report, "Biomedical Science and Its Administration." Much of this section is devoted to the Cancer Chemotherapy National Service Center. The reviewers did not judge the CCNSC unsatisfactory, but they blamed its patent policies in part for the lack of followup of possible anticancer drug effects.

"It should be noted that many compounds found to have no carcinotoxic activity but which possess other biological activity have not been studied further because of patent, contact, and other restrictions." Page 87.

As an alternative to these types of procedures, many academic scientists in the field of medicinal chemistry, are turning to their academic colleagues in pharmacology for such screening as can be had; but I would emphasize that no university to my knowledge is so organized as to be in a position to develop a new drug from the moment of the inception of the idea of the structure to the final dosage form. Furthermore, I personally do not believe that any university should be so equipped or so engaged. This is essentially not the function of university research.

I need not belabor this point; most compounds synthesized will have no practical value as medicinal agents. Nonetheless, you have already heard in these committee hearings or from other sources of the basic discoveries that have gone from the university laboratory to the patient by the collaboration of industry with the university; these include such items as insulin, discovered at the University of Toronto, "Theelin" discovered by Dr. Doisy's group at St. Louis University, cyclopropane discovered by a group of scientists at Purdue, "Benadryl" synthesized by Dr. George Rieveschl while at the University of Cincinnati, and chloramphenicol ("Chloromycetin") discovered by Dr. Burkholder at Yale University. For every success, there have been thousands of examples of lack of success; yet for every single drug so conceived and ultimately marketed, there has been remarkable relief for thousands, yea, millions of sick people. I believe that the policy developed in the Congress as a result of these hearings and other studies should leave the door open for such future contributions.

As an indication of the type of difficulty that the academic scientist encounters in the evaluation of his compounds currently, I am submitting as appendix III a copy of a letter in reference to the matter of the antiviral agents previously mentioned above; please note the sentence in the second paragraph which indicates that this group, the U.S. Army Chemical Research and Development Laboratories at the Army Chemical Center, Md., "can only assay compounds of proven antiviral activity." This is one of many letters that I wrote at the suggestion of an official at NIH in an effort to derive suitable means of testing our compounds. Needless to say, I cannot disagree with the Director of Research of this group, for he has a mission-oriented program. Nonetheless, this offers the individual academic scientist little hope of success in obtaining biological screening for his yet unproved compounds.

Even if the academic scientist manages somehow to overcome all of the difficulties in getting a compound screened, and it is found that his compound has significant activity, this is only the beginning.

After the first promising indications of biological activity have been uncovered, many additional studies must be carried out before the compound can ever reach the hands of the medical profession for the treatment or prevention of disease.

Among such studies, which are customarily carried out by the pharmaceutical industry, are further testing in several different animal species, metabolic studies, various subacute toxicity and chronic toxicity studies, development of commercial methods of synthesis, formulation into pharmaceutical dosage forms and finally, most important of all, the completion of broad clinical studies sufficient to prove the efficacy and safety of the potential new drug in human patients to the satisfaction of the FDA.

Such development programs can take years to complete and the costs can run from $500,000 to $3 or $4 million or more.

I assume there has been or will be detailed testimony from pharmaceutical executives on the difficulties and the costs of drug development, and I will leave such testimony to the industry witnesses.

I would not want the Subcommittee on Patents, Copyrights, and Trademarks to overlook the fact that the country's universities and medical schools can play a very useful role in administration of these complex patent issues if Congress sees fit to permit this.

Increasingly large numbers of universities are financed primarily with public funds, either State or Federal. Today, the patient policies of many universities reflect a strong public interest philosophy which is asserted in negotiations with pharmaceutical houses for commercial rights to therapeutic agents discovered in collaborative university-industry research. For the universities to enter into such agreements it is necessary, of course, for them to have title to the inventions either because no Federal interest was involved or because the Federal interest was waived by the granting agency's head.

In both kinds of cases, licenses agreed to by universities usually provide for a reasonable period of market exclusively (1) to compensate the cooperating company for its development costs, (2) to acknowledge the company's participation as a partner in the original research, and (3) to insure prompt development of the compound into a useful therapeutic agent.

In turn, under these agreements, the company pays royalties to the university and a major portion of them are plowed back by the university into its various research and educational programs.

At times, university policy provides that the individual inventor or inventors may share appropriately in the royalties paid by the pharmaceutical company.

The traditional collaborative research programs of university and pharmaceutical scientists have worked well in the past, before the Federal involvement became so great as to create a bar to such collaboration. I believe the principles that have guided this collaboration in the past should be applied by Congress to the patent policy now being worked out for Federal agencies.

Specifically, I believe that patent rights, certainly most of them, arising from Public Health Service (NIH) grants to university personnel should be released by the Public Health Service, with reasonable safeguards, to the universities.

If desirable, a period of market exclusivity would be negotiated by the university with a commercial company. Royalties would be paid to the university.

In every instance, of course, the Federal Government would obtain a nonexclusive, royalty-free license for its use.

Under a procedure of this kind, the public would be served by expeditious marketing of new drugs, by having private funds funneled into university programs, and by having Government retain a nonexclusive license for its own use.

I hope that any patent bill which emerges from these important hearings contains provisions authorizing such a procedure, particularly in the health field which is so crucial to all of us.

SPECIFIC COMMENTS ON THE PENDING LEGISLATION IN THIS AREA

Section 3(b) (3) of S. 1809 (Senator McClellan's bill) reserves to the contractor not less than "an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention." If the contractor is an academic institution, such a nontransferrable license is meaningless, since no university or medical school is in a position to practice an invention in the sense intended by this provision.

Obviously, the license accorded to a university must be transferrable to accomplish the intent of the provision.

Another serious objection to S. 1809 is section 4(a)(2), which prohibits any contractor, including a university or medical school, from acquiring any rights to a discovery in the health field and reserves such rights to the Government except in "exceptional circumstances."

The field of health should not be singled out for tighter control by the Federal Government. The patent system and the incentives created by it should be brought to bear more in the field of health than in any other, not less.

At the very least, this clause should be modified to enable universities with public-interest patent policies to retain rights to inventions derived from Government supported research for exploitation under reasonable terms.

General grants for the provision of original facilities and the expansion of existing facilities for university education and research programs are designed to strengthen these institutions and enable them to play an effective role in the national economy and the national security.

In this connection, I should like to quote from title VII of the health research facilities bill as originally passed by the Congress—section 701(a) and (b):

"SEC. 701. (a) The Congress hereby finds and declares that (1) the Nation's economy, welfare, and security are adversely affected by many crippling and killing diseases, the prevention and control of which require a substantial increase, in all areas of the Nation, of research activities in the sciences related to health, to house such activities are inadequate.

"(b) It is therefore the purpose of this title to assist in the construction of facilities for the conduct of research in the sciences related to health by providing grants-in-aid on a matching basis to public and nonprofit institutions for such purpose."

The provision of adequate university research facilities in today's world is a very costly undertaking and one that has been achieved in substantial measure by the use of private funds, supplemented to whatevery extent is found necessary with Federal funds. The donors of funds for such general grants, either private or government, do not intend that rights stemming from research conducted in such institutions become the property of the donors. The purpose behind the expenditure of such funds is accomplished when the institution becomes effective

in its role of education and research. The fruits of such research, in the form of royalties from patent rights, serve to reduce the financial burden on the institution and thereby to reduce the sum necessary for maintenance and expansion of the facilities for further research efforts. These institutions thereby become more nearly self-sustaining.

Equipment and facilities for conducting research are capable of reuse many times. They are not in the category of "disposables." For example, an instrument (such as a Parr hydrogenator) used for a specific federally financed research project is not to be discarded when the project is completed. Nor is it practicable to return it to the source from whence it came. Present practice is for the title to such equipment to be invested in the grantee either during the course of the investigation, at the end of the investigation, or by negotiation at the end of the project. It would be rather incongruous for the Government to attempt to confiscate patient rights arising out of nonfederally financed research merely because such equipment may subsequently be used on a nonfederally financed project.

Even the foremost advocates of a "government take all" policy would probably agree that it is the specific federally financed research project and not the financing of facilities for general or specific separately indentifiable federally financed research projects that is the area of concern about title to inventions.

When the foregoing arguments are made to those in various Government circles, the conclusion seems so clear that several have indicated that it should be unnecessary to express this concept in legislation. Yet HEW policy, as outlined earlier in a copy of the patent agreement document, frequently delays action on such situations.

There has been substantial confusion concerning exclusive rights in cases where nonfederally supported research carried on cooperatively between industry-sponsored university grantees and industry sponsors involve some contact with federally supported grants or where federally financed equipment or facilities have been used in conducting nonfederally financed research. The following are illustrative examples of typical situations:

1. Where the field of nonfederally financed research and development is not related to a prior or concurrent federally sponsored research and development program, in the same institution by the same or different grantees.

This covers those situations where the nonfederally supported program is totally different from the federally supported program but the same grantee or contractor is involved. For example, a grantee may have a grant from the NIH to conduct research in the area of one disease, and subsequently or concurrently he receives a nonfederally supported grant to conduct research in the area of a related disease. While there appears to be a clear-cut division of the equities, the experience of non-Federal grantors has been that NIH personnel are reluctant to agree that the rights should remain with the grantee or contractor in either instance.

2. Where the fields of research and development are related but the research and development programs are different.

The grantee has a federally and nonfederally supported grant in the same general area, for example, research concerning a particular virus. The nonfederally supported grant is for a specifically defined program which does not overlap with the scope of the research program included in the grantee's application for a federally supported grant. The grants may be concurrent or consecutive. Situations of this type have formed a major area of uncertainty.

3. The program is conducted in or with facilities or equipment originally purchased, built, or acquired with Federal funds for general use or for use in connection with a prior or concurring Government-sponsored research project.

(*a*) Under a prior Federal grant the nonfederally supported grantee's institution built the laboratory in which the nonfederally supported grantee is working.

(*b*) Under a prior federally supported grant, the grantee or his institution purchased or acquired laboratory equipment which has remained in the laboratory of or is accessible to the nonfederally supported grantee. This equipment is then used by the grantee on a nonfederally supported grant.

These aspects are brought out rather clearly in the proposed amendment to H.R. 2984, section 3(b) (1), which stated:

"(b) (1). No part of any appropriated funds may be expended pursuant to authorization given by this act for any scientific or technological research or developmental activity unless such expenditure is conditioned upon provisions effective to insure that all developments resulting from that activity will be made freely available to the general public. The Secretary of Health, Education, and Welfare shall include in each grant or contract made or entered into under such authorization for any such activity provisions under which the United States will acquire exclusive right in and to any such development. Nothing contained in this paragraph shall be construed to deprive the owner of any background patent relating to any such activity, without his consent, of any right which that owner may have under that patent."

It is believed that the resolution of the foregoing situations should be mandatory and not discretionary, assuming of course that the Government agency can satisfy itself that the circumstances are as represented.

In this connection, I should like to offer for your consideration a specific suggestion as an addition to pending legislation so as to clarify this area.

I believe that the exclusive rights in and to developments stemming from nonfederally supported research and development should remain with the grantee or the sponsor where the field of research and development is not related to a prior or concurrent Government-sponsored research and development program or where the fields of research and development are related but the research and development programs are different. The exclusive rights in and to a nonfederally supported research and development program should not be lost by the grantee or the sponsor because the program is conducted in or with facilities or equipment originally purchased, built, or acquired with Federal funds for general use or for use in connection with a prior or concurring Government-sponsored research project.

At this point, I should like to offer one other suggestion for consideration. Perhaps the members of this committee will recognize this clearly as an indication of my own naivete in regard to this pending legislation.

It appears that one of the great concerns is that of the giveaway of inventions based on Government grants to assist in the financing of research. Personally, I believe, as indicated elsewhere in this statement, that the major purpose in such research expenditures is accomplished when the institution or institute becomes effective in its role of education and/or research. I recognize that this is not so clearly the case when the grant is made by a highly mission-oriented agency of the Government. Nonetheless, in the normal course of events, when industry sponsors research in the area of medicinal chemistry in a university, clear recognition is given to the contribution of both sides. The university gets title to the invention, but an assignment is generally made in order to develop the invention most effectively. Now, despite the fact that industry may have already made a substantial contribution in the way of a grant in the development of the research, the final contract usually contains a proviso in which the institution shares in the profits made and the individual investigator also receives a share for his contribution to this in the form of the idea and the creative ingenuity that allowed for the development of the idea.

In the jointly sponsored industry Government projects or those sponsored by industry in a facility constructed with Federal funds, I believe that a part of the difficulty could be resolved by a policy that would require industry, if it wishes to acquire exclusivity, to repay the amount of the Government grant plus a negotiated percentage. Certainly, under these conditions, the people of our country could, in essence, have their cake and eat it. The funds expended by the Government would be recouped together with a reasonable percentage. This would, of course, have to be negotiated in each instance, due to the different circumstances involved in virtually each case, and then the patents could, where appropriate, be assigned to the university, a public institution devoted to the welfare of the whole, and these could then be reassigned, for an appropriate period, to the cosponsoring industry with a period of exclusivity which would encourage the risk-taking or venture capital necessary for development of the idea. The Government would be repaid monetarily by having its contribution, in dollars, rebated and by seeing more rapid developments take place insofar as the production and marketability of items designed to improve the health and welfare of the American people. Thus, a joint venture of the Government, industry, university,

and the private citizen, the investigator, would be encouraged, and all Americans would benefit. Such a proposal, as indicated at the outset, probably reveals a very naive approach to a quite complex problem, but I do believe sincerely that it could be made to work when men of good will set themselves to this task.

I can understand that this subcommittee, indeed all Federal officials with responsibility in this field, have concluded that health is different and that special steps should be taken to encourage programs where the lives and well-being of our citizens are concerned. I understand that it was because of the realization that health is different that the patent policy memorandum adopted by our late President Kennedy in 1963 established separate and special treatment for inventions in the field of health.

But it seems to me that this special treatment adopted in the Kennedy memo and carried forward in the McClellan bill, S. 1809, will have a result directly opposite from that intended by our late President and by the chairman of this subcommittee.

During the 175 years in which our country has had a patent law, it has become clear that patents do create progress, as our Founding Fathers were confident they would when they wrote section 8 of article 1 of our Constitution.

And if it is true that patents in general create progress in general, it is no less true that patents in the health field create progress in the health field. It would, therefore, seem far more sensible to expand the patent incentive in this field of health, with its special implications for the lives and happiness of all of us, than to remove or diminish the patent incentive that stimulates the discovery of new drugs.

Section 8(b) provides that a Federal agency head may grant an exclusive or nonexclusive license for the practice of any invention for which he holds a patent acquired under S. 1809.

This section should be modified to require each agency head to issue licenses with reasonable periods of exclusivity (1) when the contribution of funds, personnel, and facilities of either or both the university and/or cooperating industrial organization has been greater than the contribution of the Government to the making of the invention, or (2) when additional expenditures of non-Government funds will be necessary to develop the invention to the point of practical application and the granting of such reasonable exclusivity to the university and/or cooperating industrial organization is likely to assure or accelerate development of the invention and availability for public use.

To the extent that any contractor might attempt to abuse the rights retained and period of exclusivity, a compulsory licensing system, as is indicated in most of these pieces of legislation, as proposed could certainly be effectively utilized.

In regard to the above, the period of exclusivity is important. Once again, I cite a personal case, that of the synthesis of amopyroquine, a drug possessing antimalarial activity. This was synthesized by me as a graduate student at the University of Kansas in 1952. While I recognize that this is an exceptional case and also that the field of antimalarials was not a particularly "hot" one during the mid-1950's, it took a period of almost 10 years from synthesis to marketability. While this may be the exception rather than the rule, I simply cite it for the committee as some sort of guideline with regard to the establishment of the desirable period of exclusivity. With a very limited period of exclusivity, such a compound would never have reached the stage, in all likelihood, that permitted this compound to be tested by Dr. M. T. Hoekenga as was reported by him in the American Journal of Tropical Medicine and Hygiene in 1957. Admittedly, this may be a "marginal" drug, but, in some instances, it was able to accomplish results not achieved with other, according to Dr. Hoekenga's reports.

One of my major concerns in the enactment of such legislation is that we will not have such situations as existed for a great many years in which papaverine was treated as a narcotic by Federal law simply because it was derived from opium—yet it did not possess addicting tendencies. Similarly, the undesirable situation in which a prescription was required for Elixir of Benadryl (12.5 mgm. per teaspoonful dose) when one could purchase, over the counter, under sanction of Federal law the same drug, insofar as active constituent was concerned, in a tablet form containing 50 mgm. per does. I recognize that such discrepancies do exist under any "umbrella" type legislation; that is why I believe that

flexibility must be built into the framework of patent legislation if it is to be successful and accomplish its purpose.

In support of this concept of flexibility, I should like to enter the following excerpts from the testimony of Congressman Daddario before the House Committee on Public Works re water pollution control on February 15, 1965:

"Prior to the Atomic Energy Act of 1946 no Federal departmnt or agency was required by its organic act to handle rights to inventions growing out of its activities in any special way. This was left up to the agency, which could bargain for any patent right is wanted. As a matter of practice it was found most expedient to secure for the Government a royalty-free, irrevocable license to use, make or employ such inventions—either through the inventor-contractor or any other party chosen by the Government. Today every entity of Government always secures this right. Usually this is all the Governmnt wants, needs, or can use. In such cases title to the invention itself is left to the contractor—and he can patent it, if it is patentable, subject always to the Government's right to use it without charge.

"I am sure it is evident that the administration's balanced effort here is undercut badly by legislative provisions such as the patent amendment in this bill. The fact is that this provision is extremely rigid in its effect and is quite unfair in that it looks only on one side of the coin. Moreover, this amendment does not really prevent "giveaways," as is alleged, but to some extent promotes them—especially in the foreign market and at a time when we are seriously concerned about our balance of payments.

"If there is one thing that we have learned in our study of the matter, and with which the administration concurs and insists upon, it is the need for flexibility in our patent approach. We must have this, not only in order to be equitable in our relations with industry, agriculture, and labor, but in order to acquire sufficient experience on which to base general patent legislation if that becomes deisrable. We cannot be equitable and we cannot gain the necessary experience without administrative flexibility. The Senate amendment (re: S. 512) denies us this resource. It places all property rights in inventions connected with the pollution program in the public domain regardless of the fact that such inventions are freely available to the Government for public use anyhow. Its stipulation that no contractor be deprived of his "background patents" is virtually meaningless since there is no fixed definition of "background patents" and, in any case, the Government must often allow contractors foreground rights in exchange for "background" privileges in order to make the invention worthwhile.

"What else happens when flexibility is denied?

"For one thing, the Government may have to deal with reluctant contractors who tend to compartmentalize their Government research and isolate it from their most promising commercial ideas. We know, for example, that in many instances private contractors will separate their research teams working on Government projects from their other researchers working strictly on commercial ones. This happens mainly because the contractors feel the need for legal protection of their most profitable investments.

"For another, we fail to take into account that different Federal agencies have different missions and must handle their contractors in different ways. We need a single standard for guidelines, certainly, but a standard that permits enough flexibility to get the mission done. This is the most important matter.

I believe that the need for flexibility in the matter of public health is certainly equally great.

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of governmental legislation leading to the governmental ownership of the patent, whether partially or completely supported by Federal funds, defeats the basic purpose of research in the field of medicinal chemistry. Such procedures constitute a serious deterrent to essential collaboration between the Government, industry, and the universities and thus to the health of the Nation in the long run.

In addition, one might examine the basic philosophy to ascertain if such restrictions do not, in fact, violate simple legal and moral concepts. Does not the researcher hold the fundamental right to his invention? Is not something of human dignity lost when the Government confiscates—call it anything you

will, but it appears to me to be confiscation—an individual's knowledge in exchange for partial financial support?

It appears to me that all too much attention has been directed to the rights of the Government to the neglect of the right of the inventor, of his institution, and of others who may be concerned in the overall process. Can unilateral action on this front by the Congress, without due consideration of all these factors, be truly in the best interest of the Nation? The Congress fostered the foundation of the Federal agencies and supports them annually with appropriations derived from tax dollars. Thus, the Congress is charged with the responsibility of protecting the interest of the Government, true. But who, I ask, if not the Congress also, is to protect the interest of the individual, the academic institution, and the sector of industry vitally interested in these matters?

In conclusion, I should like to express my deep appreciation to the members of this committee for allowing me this opportunity of presenting my views on this most important segment of governmental activity.

APPENDIX I

CURRICULUM VITAE OF WILLIAM LEWIS NOBLES

William Lewis Nobles, dean of the graduate school and professor of pharmacy and pharmaceutical chemistry, the University of Mississippi, University, Miss.

Date and place of birth: Meridian, Miss., on September 11, 1925.

Married: Two daughters, Sandra, age 13, and Suzanne, age 7.

Education: Meridian Junior College, 1942–45; University of Mississippi, 1943–44; Ursinus College, Collegeville, Pa., 1944–45; University of Mississippi, B.S. in pharmacy, 1948; M.S., 1949; University of Kansas, Ph. D., 1952; University of Michigan, 1958–59, under a National Science Foundation postdoctoral award.

Professional experience: Teaching assistant, University of Mississippi, 1948–49; assistant professor, University of Mississippi, 1952–54; associate professor, University of Mississippi, 1954–55; professor, University of Mississippi, 1955–present; dean of the graduate school, September 1960–present; coordinator of university research, April 1964–present.

Honors: Sigma Xi; American Foundation for Pharmaceutical Education fellow while at the University of Kansas; Gustavus A. Pfeiffer Memorial Research fellow, 1955–58; 1959–60; National Science Foundation Postdoctoral fellow, University of Michigan, 1958–59.

Memberships held: Sigma Xi, Rho Chi, American Pharmaceutical Association, American Chemical Society, Chemical Society (Great Britain), American Association for the Advancement of Science, and the New York Academy of Science.

Publications: Total, 65. The last five are:

W. Lewis Nobles and B. Blackburn Thompson, "Mannich Bases and Alcohols From Hexamethylenimine" (J. Pharm. Sci., 53, 1154).

Heino A. Luts and W. Lewis Nobles, "Heptamethyleneimine in the Mannich Reaction I. Substituted β-Amino Ketones and Substituted γ-Amino Alcohols" (J. Pharm. Sci., 54, 67 (1965)).

W. Lewis Nobles, B. Blackburn Thompson, "Application of Mannich Reaction to Sulfones I. Reactive Methylene Moiety of Sulfones" (J. Pharm Sci., 54, 576, (1965)).

C. DeWitt Blanton, Jr., and W. Lewis Nobles, "Use of 3-Azabicyclo[3.2.2.]nonane in the Mannich Reaction IV. Additional Derived Products" (J. Pharm. Sci., 53, 1130 (1964)).

Charlotte H. Bruening and W. Lewis Nobles, "Synthetic Relatives of Reserpine" (J. Pharm Sci., 54, 925 (1965)).

APPENDIX II

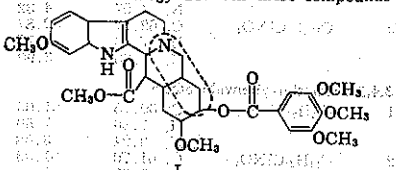
[Reprinted from the Journal of Pharmaceutical Sciences,
Vol. 54, No. 6, June, 1965.

Synthetic Relatives of Reserpine

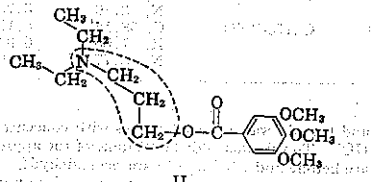
By CHARLOTTE H. BRUENING and W. LEWIS NOBLES

A group of Mannich bases, containing the 3,4,5-trimethoxyphenyl moiety as in reserpine, has been synthesized. Preliminary pharmacological screening suggests that one of the group, the morpholine Mannich base from 3,4,5-trimethoxybenzalacetone, demonstrated certain CNS depressant effects in mice, indicating that it might be considered as a tranquilizing agent for further studies.

MILLER AND WEINBERG (1) reported that 3-(*N,N* - diethylamino)propyl - 3,4,5 - trimethoxybenzoate (II) possessed approximately one-third of the tranquilizing action of reserpine (I). The structural analogy between these compounds



I



II

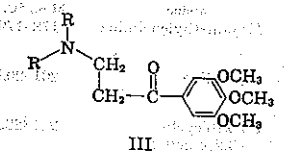
would indicate that some tranquilizing activity resides in a relatively small portion of the reserpine molecule. Since this report there have been several hundred publications dealing with the biological activity of compounds containing the trimethoxybenzoyl moiety of the parent molecule. Many of the aspects of this work have been reviewed by Schlager (2).

Recorded in the literature (3–11) are numerous ketonic Mannich bases, prepared for pharmacological testing as antispasmodics, analgesics, chemotherapeutic agents, and local anesthetics. Such compounds may in general be prepared readily by means of the Mannich reaction which utilizes the appropriate ketone, formaldehyde, or paraformaldehyde and the desired amine. This may be illustrated as follows:

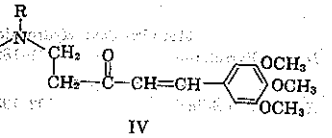
$$RCOCH_3 + HCHO + R'_2NH \cdot HCl \rightarrow RCOCH_2CH_2NR'_2 \cdot HCl + H_2O$$

The rather extensive literature dealing with this reaction has been reviewed by Blicke (12), Reichert (13), and Hellmann and Opitz (14).

In an effort to prepare synthetic relatives of reserpine utilizing the Mannich reaction, Mannich bases were prepared from 3,4,5-trimethoxyacetophenone and 3,4,5-trimethoxybenzalacetone. The structural analogy, albeit limited, can be easily seen from an inspection of the following structures (III and IV) and a comparison of them with the parent structure (I) above.



III



IV

PHARMACOLOGICAL RESULTS

The three Mannich bases (*A–C*) obtained from trimethoxyacetophenone were subjected to a study of preliminary dose effects, pernicious preening, and maximal electric shock seizure utilizing Swiss-Webster mice.

With compound *A*, the oral administration of 250–2000 mg./Kg. produced asphyxial-like convulsions, cyanosis, and death within 4–10 min. The administration of 500–2000 mg./Kg. of compound *B* elicited ataxia, muscle weakness, asphyxial convulsions, cyanosis, and death. Dosages in the range of 250–2000 mg./Kg. of compound *C* elicited tonic-clonic seizures, motor deficits, followed by increased activity, tremors, cyanosis, asphyxial seizures, and death. Lower doses (100 mg./Kg.) produced CNS stimulant effects. Hypothermia followed doses of 500 mg./Kg. or greater of compound *C*. Compound *C* demonstrated enough activity to warrant further testing for analeptic activity.

Oral or intraperitoneal administration of 500 and 2000 mg./Kg., respectively, elicited no significant overt effects. Oral administration of 2000 mg./Kg. of compound *E* produced slight reduction in motor activity, lachrymation, muscle weakness, tremors, marked hypothermia, champing, and asphyxial seizures, terminating in death. Lower doses to 500 mg./Kg. were marked by slight lachrymation and motor disturbances.

Because of the particularly interesting activity demonstrated by 3,4,5-trimethoxybenzoyl morpholide in the work of Vargha (15), the Mannich base prepared from morpholine and the trimethoxybenzalacetone was subjected to intensive screening by Hazleton Laboratories, Inc.[1] For this compound, the estimated LD_{50} was found to be 112 mg./Kg. Analysis of the rat pharmacodynamic record showed that this compound elicited a transient

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[1] The preliminary biological data on compound *F* were provided by the Hazleton Laboratories, Inc., under the supervision of the Scientific Staff, Psychopharmacology Service Center, and was supported under contract PH 43-63-555 from the National Institute of Mental Health, U. S. Public Health Service, Bethesda, Md.

TABLE I

Mannich Base Hydrochlorides of 3,4,5-Trimethoxyacetophenone

Compd.	Amine	M.p., °C.	Yield, %	Formula	Anal.	Calcd.	Found
A	Hexamethyleneimine	178–179	45	$C_{18}H_{28}ClNO_4$	C,	60.41	60.57
					H,	7.89	7.77
					N,	3.91	4.28
B	Piperidine	201–202	69	$C_{17}H_{26}ClNO_4$	C,	59.38	59.46
					H,	7.62	7.47
					N,	4.07	4.32
C	3-Azabicyclo (3,2,2)nonane	221–222	72	$C_{20}H_{30}ClNO_4$	C,	62.57	62.87
					H,	7.88	7.77
					N,	3.65	3.90

Mannich Base Hydrochlorides of 3,4,5-Trimethoxybenzalacetone

D	Pyrrolidine	181–182	41	$C_{18}H_{26}ClNO_4$	C,	60.75	61.05
					H,	7.36	7.50
					N,	3.94	3.98
E	Piperidine	192–193	42	$C_{19}H_{28}ClNO_4$	C,	61.70	61.39
					H,	7.63	7.90
					N,	3.79	3.78
F	Morpholine	195–196	60	$C_{18}H_{26}ClNO_5$	C,	58.14	58.17
					H,	7.05	6.99
					N,	3.77	3.80

hypotensive effect at all dosage levels tested. Hexobarbital sleeping time was prolonged significantly at dosages of 11.2 and 33.6 mg./Kg. Analysis of the hotplate analgesia test data revealed that this compound possessed no analgesic properties, and the electroshock studies likewise indicated a lack of anticonvulsant properties. Analysis of the actophotometer data showed that this compound decreased spontaneous motor activity at all dosages tested (3.36–33.6 mg./Kg.). This compound interfered with conditioned avoidance responses in a dose related manner. No pathological changes were observed upon gross necropsy. A summary conclusion provided by Hazleton Laboratories indicated that this agent showed certain CNS depressant effects in mice, indicating that it could be considered as a tranquilizing agent for further studies. The compound, like many CNS depressants, elicited a hypotensive effect in the rat.

EXPERIMENTAL

Basic data indicating the structure, yield, melting point, and other such items for the six compounds presented in this study are indicated in Table I. 3,4,5-Trimethoxybenzalacetone was prepared according to the method of Burckhalter and Johnson (16) for 2,3-dimethoxybenzalacetone in a yield of 55%. The Mannich bases were prepared as follows.

In a 50-ml. flask containing 25 ml. of absolute ethanol was added 0.05 mole of the respective amine, and the pH was adjusted to 3–4 with concentrated HCl. To this was added 0.05 mole of the appropriate ketone and 2.3 Gm. of paraformaldehyde. The reaction mixture was allowed to reflux for approximately 3 hr. and was then poured into 100 ml. of dry acetone. After cooling in the refrigerator overnight, the precipitate was collected and recrystallized from an ethanol–acetone mixture.

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APPENDIX III

U.S. ARMY CHEMICAL RESEARCH AND DEVELOPMENT LABORATORIES,
Army Chemical Center, Md., July 10, 1962.

DR. LEWIS NOBLES,
Office of the Dean, The University of Mississippi, The Graduate School, University, Miss.

DEAR DR. NOBLES: I wish to acknowledge the receipt of your recent letter and to apologize for not being able to answer your request more quickly. Unfortunately, the chief of the screening group concerned with the assay of antiviral activity was not available. I could not commit his group without his permission.

It is true that determinations of antiviral activity are carried on as indicated in Dr. Silver's letter to Dr. Jeffery. However, the group has become quite selective in their choice of compounds. They are, unfortunately, not in a position to test compounds of unknown activity or even those suspected of being active on the basis of the analogy. The group can only assay compounds of proven antiviral activity. These are tested against those types of virus which are of interest to our biological laboratories.

It may be that Dr. Schabel of the Southern Research Institute would be able to assist you by recommending an antiviral screening program to which your compounds could be submitted.

Most of the screening programs in the Chemical Corps are quite as selective as that described above with the exception of two. These are broad screens for the purpose of seeking out new types of structures having an extremely high biological activity or ones having pronounced herbicidal (growth regulators, phytocides, defoliants, etc.) effects. I am inclosing copies of these procedures for your retention. We would be happy to have the opportunity to screen any of your heterocyclic structures in these screens. If both screens are to be run, we would require about 3 grams of material. I am also taking the liberty of inclosing a resumé of the policies of the corps' industrial liaison program.

I am sorry that we are unable to comply with your request. Perhaps, we can be of service to you in the screening of your compounds for other purposes.

Sincerely yours,

E. A. METCALF, Ph. D.,
Chief, Industrial Liaison Office,
Directorate of Research.

Senator MCCLELLAN. You may proceed to highlight your statement, sir.

Mr. NOBLES. Well, I will just pick up abstracts, actually, from the statement.

The need to arrive at some basis for the equitable measurement of rights was not so great in health research until Federal support reached the extent that the great majority of qualified investigators in every field began to receive some of their support from one or more Federal agencies and virtually every nonprofit research center was similarly involved.

Nonetheless, wisdom in the drafting and application of Federal agencies' patent policies has always been of great importance to the scientific community. But in the last decade the growth of Federal programs for conduct and support of research and development in industry and on the campus has been so staggering that the effects of Federal policy are felt today in virtually every laboratory in every community in this country.

If the equities cannot be reasonably defined and rights judiciously assigned, that facilities of the pharmaceutical industry in certain areas may well be cut off, at least almost entirely, from the academic investigator and from those in scientific operations within the Government itself. This can only result in harm to all three.

Moving quickly to page 5, I would point to an area that the chairman raised a question about with Dr. Seevers this morning.

If a grantee synthesized an interesting chemical compound or a series of such compounds and wishes to have them screened by a pharmaceutical house, he is required to notify the Public Health Service before entering into any screening arrangement. The pharmaceutical house then is required to sign an agreement relinquishing any patent rights in the test area involved before it is permitted to undertake the screening work. A copy of such an agreement is inserted later in this statement.

A most serious result of this restrictive Federal patent policy, at a time when expansion of Federal research programs has put Federal money into a great many academic laboratories, is that many new chemicals are not being tested at all or are not being fully evaluated because drug companies are not able to undertake the work under conditions required by the patent policies of the public health service and its parent agency, the Department of Health, Education, and Welfare.

Now we want to mention specifically in this regard in just a moment. On page 7 we have abstracted a copy of the patent agreement which the Department of Health, Education, and Welfare has, which it asks that the grantee as well as the pharmaceutical company sign.

We make reference to the point that one area in which we are quite interested in our own laboratories has been that of the synthesis of possible antiviral agents. Prior to the procedure of NIH which substituted a patent agreement for clause 4(a) on the face of the sheet of the application for research grant, we had received agreement from one of the major pharmaceutical houses to test compounds synthesized under the terms of a grant from NIH for the synthesis of heterocyclic compounds as possible antiviral agents.

Following the implementation of this policy, somewhere between November of 1961 and the spring of 1962, the pharmaceutical house was placed in the position of having to indicate that they could not sign the new patent agreement, since they were concerned over the scope of its text, including the following:

"The pharmaceutical company shall be permitted to obtain patent rights to new uses of the compounds developed as its own expense, except where the grantee contributed or participated in the conception or reduction to practice of such new use, or where such new use patents would hamper, impede, or infringe on the intended use of the invention covered by the product application, or where such new use is within the field of research works supported by the grant."

I think that anyone can readily observe from this agreement that any pharmaceutical company that would agree to do this would in a sense be agreeing to donate their services without hope of compensation.

As a part of the basic proposition, the pharmaceutical chemist or medical chemist in the university is concerned with these syntheses of compounds. These are then evaluated by an agency, as described by Dr. Seevers earlier this morning. Without having this information at hand, very little progress can be made.

With the knowledge provided by the pharmacologist and others associated in the screening and evaluation of the compounds, then further work can proceed to perhaps useful devices.

But in the area in which we are working and another area, for example, that of compounds in the general area of mental health, ar-

rangements were made by the National Institutes of Health for the testing of four compounds prepared during the course of this work. In other words, NIH originally let us send two compounds in, and then two additional compounds.

As an indication of the amount of work involved in screening 3 of these 4 compounds and reporting on it, there is a document of some 55 or 60 pages. So this is the amount of work and the cost that is involved in this type of venture. As has been previously indicated, it is obviously a high-risk venture.

As an indication of the type of difficulty that the academic scientist encounters in the evaluation of his compounds currently, I am submitting as appendix III a copy of a letter in reference to the matter of antiviral agents previously mentioned. Please note the sentence in the second paragraph which indicates that this group, the U.S. Army Chemical Research and Development Laboratories at the Army Chemical Center, Md., "can only assay compounds of proven antiviral activity."

This is one of many letters that I wrote at the suggestion of an official at NIH in an effort to derive suitable means of testing our compounds.

Needless to say, I cannot disagree with the director of research of this group, for he has a mission-oriented program. Nonetheless, this offers the individual academic scientist little hope of success in obtaining biological screening for his yet unproved compounds.

I would not want the Subcommittee on Patents, Copyrights, and Trademarks to overlook the fact that the country's universities and medical schools can play a very useful role in the administration of these complex patent issues if Congress sees fit to permit this.

I would like to move rapidly to page 12 with some specific comments on the pending legislation in this area.

One allusion has already been made, but since it was by a nonacademic witness, I would like to make it from the standpoint of the academic, university community.

Section 3(b)(3) of S. 1809 reserves to the contractor not less than "an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention." If the contractor is an academic institution, such a nontransferable license is meaningless, since no university or medical school is in a position to practice an invention in the sense intended by this provision.

Another serious objection to S. 1809 of section 4(a)(2), which prohibits any contractor, including a university or medical school, from acquiring any rights to a discovery in the health field, and reserves such rights to the Government except in "exceptional circumstances."

We do not feel that the field of health should be singled out for tighter control by the Federal Government. The patent system and the incentives created by it should be brought to bear more in the field of health than in any other.

Then I wanted to pick up at the bottom of page 12 and page 13 of the printed statement, regarding title VII of the health research facilities bill as originally passed by the Congress. The intent is expressed there in just one sentence:

> It is therefore the purpose of this title to assist in the construction of facilities for the conduct of research in the sciences related to health by providing—

grants-in-aid on a matching basis to public and nonprofit institutions for such purpose.

The provision of adequate university research facilities in today's world is a very costly undertaking, and one that has been achieved in substantial measure by the use of private funds, supplemented to whatever extent is found necessary with Federal funds. The donors of funds for such general grants, either private or Government, do not intend that rights stemming from research conducted in such institutions become the property of the donors.

The purpose behind the expenditure of such funds is accomplished when the institution becomes effective in its role of education and research. The fruits of such research, in the form of royalties from patent rights, serve to reduce the financial burden on the institution, and thereby to reduce the sum necessary for maintenance and expansion of the facilities for further research efforts.

We want to move quickly to a conclusion on this. We would like to cite particularly one problem, however, and that is brought out in the proposed amendment to Senate bill 512, relative to the health research facilities.

This is a very basic problem for all of the colleges and universities; that is, that it spells out specifically in the Senate bill or the proposed amendments to S. 512—I cannot find the language of it right now—that:

No part of any appropriated funds may be expended pursuant to authorization given by this act for any scientific or technological research or developmental activity unless such expenditure is conditioned upon provisions effective to insure that all developments resulting from that activity will be made freely available to the general public.

Now, virtually every medical school in the country, chemistry departments and schools of pharmacy, have received support in the building of research facilities. A real question in the mind of everyone, then, is about the possible implication of carrying on nonfederally supported research in these facilities which were built partially with Federal funds.

The language of the proposed amendment, as it was proposed earlier in this session of Congress, would tend to indicate to us that if the Federal support went into the building, any moneys that might be channeled into a research program by non-Federal funds might be impaired by this.

The last thing that we would like to move to is right at the bottom of page 20 and on page 21 at the closing of our statement.

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of governmental legislation leading to the governmental ownership of the patent, whether partially or completely supported by Federal funds, defeats the basic purpose of research in the field of medicinal chemistry. Such procedures constitute a serious deterrent to essential collaboration between the Government, industry, and the universities, and thus to the health of the Nation in the long run.

In addition, one might examine the basic philosophy to ascertain if such restrictions do not, in fact, violate simple legal and moral concepts.

Does not the researcher hold the fundamental right to his invention?

Is not something of human dignity lost when the Government confiscates—call it anything you will, but it appears to me to be confiscation—an individual's knowledge in exchange for partial financial support?

It appears to me that all too much attention has been directed to the rights of the Government, to the neglect of the right of the inventor, of his institution, and of others who may be concerned in the overall process. Can unilateral action on this front by the Congress, without due consideration of all these factors, be truly in the best interest of the Nation?

The Congress fostered the foundation of the Federal agencies and supports them annually with appropriations derived from tax dollars. Thus, the Congress is charged with the responsibility of protecting the interest of the Government, true. But who, I ask, if not the Congress also, is to protect the interest of the individual, the academic institution, and the sector of industry vitally interested in these matters?

I appreciate the opportunity of appearing before the committee and of having our statement incorporated in the record, Mr. Chairman.

Senator McClellan. Thank you very much, Dean Nobles. I am sure you have some very valuable information in your statement. I have not had the opportunity to read it, but I hope to review the many statements that have been submitted and to try to study the whole record.

We appreciate very much your contribution to the committee's work.

Mr. Nobles. Thank you, sir.

(The following was subsequently reviewed and ordered printed at this point by the chairman.)

The University of Mississippi,
The Graduate School,
University, Miss., August 25, 1965.

Hon. John McClellan,
Chairman, Committee on Patents, Trademarks, and Copyrights,
Senate Office Building, Washington, D.C.

Dear Senator McClellan: Indeed, I want to express my appreciation for the opportunity of appearing before your committee last Thursday with respect to the effect of pending legislation on patents, as it relates to university situations. I deeply appreciate the very fine way in which you conducted the hearing; I know that the hearings on this and related bills with which you are concerned certainly must be a tremendous drain on your time and effort. Nonetheless, I do deeply appreciate the opportunity of presenting our viewpoints on this matter.

Upon my return, one other item has come to my attention which may be of some significance. I recall that you indicated that the record would remain open until August 31, and I am submitting this as perhaps an additional idea to be included in considerations of the staff with respect to researching the testimony relative to the bill that might be brought forth.

It appears to me very definitely that the patent right is really the right to exclude, and not to include. I do not see that the Government really has a need for the right to exclude on a general basis, since obviously this can be done in case of great national interest on a specific piece of pending legislation. Contrariwise, it is definitely the university, and possibly the pharmaceutical industry in the case of this bill, who need the right in order to provide the incentive to invest substantial funds—on the part of industry—in developing marketing of the drug and for the university, a source of potential revenue for the support of further research and the extension of physical facilities. I believe that this is a rather significant point, and it should be borne in mind that a patent is not like a stock certificate or a savings bond. There is no value in putting the patent into a safe deposit vault. To be of any value it must be used; the invention must be exploited, and thus made available to all who can derive value from it.

In my opinion, the mere right of patent itself will not insure use unless the right to exclude is brought into play.

I would reemphasize the fact which I made in my formal presentation to the committee that if the Government takes title to the patent and freely grants license to all comers, few industries—particularly those in the high-risk pharmaceutical industry—are likely to become interested in exploiting the invention. This could mean, for example, with regard to an important drug that the public might be deprived of the benefits of that drug. Again, this points out the importance of understanding that a patent is truly the right to exclude.

I would reemphasize the importance of this from the academic standpoint, in that unless the university by right of assignment of the patent and possible transfer for an exclusive period to an industry is so authorized, it will suffer irreparable harm in the lack of cooperation that has been evident, certainly in the last 20 years, between the academic institutions and the pharmaceutical industry.

In my formal statement I presented two or three specific instances of failure of cooperation in the last few years, based on questions regarding the impending patent policy and interpretations that were being given currently by HEW on this point. Doubtless these same facts could be elicited from hundreds—even thousands—of scientists in my particular field and those of related areas with respect to their experiences during the last few years.

I hope that consideration will be given to these points in the drafting of legislation in connection with this matter. Again, I should like to thank you for the courtesies extended me and the very fine atmosphere in which the hearings of the committee were conducted.

Sincerely yours,

LEWIS NOBLES, *Dean.*

Senator MCCLELLAN. The Chair will make this brief statement.

This concludes the public hearings that the subcommittee has scheduled to date on the pending patent policy bill.

During 7 days of hearing, we have received testimony from 38 witnesses, and a number of statements have also been submitted by others for inclusion in the record.

I am informed by the staff that over 100 individual amendments have been specifically proposed and submitted for the committee's study. The transcript of these hearings already covers over 800 pages.

I have no desire to delay action on this subject. However, if a thorough and judicious consideration is to be given to the evidence that we have heard, if the suggestions we have received are to be carefully weighed and evaluated, and if a sound and equitable bill is to be reported, it will obviously be necessary that extended and careful study be given to this entire record.

The chairman will therefore consult with the other members of the subcommittee regarding our further procedure and deliberations. How soon the subcommittee can begin meetings to consider markups of the bill and how long it will take the subcommittee to complete such markup, I just cannot say. I would not even attempt to predict at this time how soon the subcommittee can make its report.

The record, however, will remain open until August 31. If anyone desires to submit any further evidence, any statements, we will receive them and consider whether they are appropriate for the record. If they are, they will be admitted to the record; if they are not, somebody will have wasted his time.

The subcommittee will meet this afternoon at 2 p.m. to continue hearings on the copyright revision bill. The subcommittee stands in recess until 2 p.m.

(Whereupon, at 12:15 p.m., the subcommittee was adjourned.)

APPENDIX

AMERICAN COUNCIL ON EDUCATION,
COMMISSION ON FEDERAL RELATIONS,
Washington, D.C., July 20, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: Enclosed is a brief statement by the American Council on Education, indicating the position of the council on various patent bills and in particular on S. 1809.

We hope very much that this statement may be made a part of the record of the hearings held before the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee.

May I take this opportunity to commend you and the members of the subcommittee for devoting such careful attention to this complex problem.

Sincerely yours,

JOHN F. MORSE,
Director of the Commission.

Enclosure.

STATEMENT BY THE AMERICAN COUNCIL ON EDUCATION ON S. 1809, THE FEDERAL INVENTIONS ACT

The American Council on Education[1] wishes to commend the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee for the study and careful consideration it has given to S. 789, S. 1809, and S. 1899, concerning rights to inventions derived from Government-financed research and development. We believe it is desirable and should be possible to develop legislatively, as a result of these hearings, a uniform and stable Government patent policy and to eliminate specific conflicting procedures required by existing laws. In particular we wish to express our support for the Federal Inventions Act, S. 1809, and to suggest certain amendments thereto.

The Federal Government, through its sponsorship of research conducted in universities, has the objective of expanding the boundaries of existing knowledge in areas or on problems deemed in the public interest or related to national goals. The research results are generally made available to all, and the university is free to punish them. The sponsoring agency receives agreed upon reports in fulfillment of the agreement. The occurrence of an invention during the course of the reserch is above and beyond the objectives of the research agreement; in short it is a "byproduct" of the research activity, largely attributable to the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment provided by the university.

Even though inventions are not necessarily the objective of academic studies, patentable discoveries do arise. When they do, the equities to be recognized include those of the inventor, the university, and, very properly, the sponsors providing financial support for the particular research project most closely related to the discovery. Some of the difficult problems ordinarily involved in the assignment of patent rights as between the Federal Government and its industrial contractors are absent in the case of the colleges and universities. This is so, first, because educational institutions are not themselves organized to manufacture or produce and market the patentable invention. Rather they must

[1] The American Council on Education, a voluntary, nongovernmental body, is the principal coordinating agency for higher education in the United States. It has a membership of 1,113 colleges and universities and 230 education organizations.

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seek to interest those in the industrial world who have this capability. This is often a difficult task, since few inventions coming out of university research offer prospects of a large market or a high return on investment. These problems are absent also because of the nonprofit nature of the universities and because they exist to serve the interests not of their stockholders but of the public.

In seeking to fulfill their obligations in teaching, research, and public service, the universities and their faculties generally recognize their public responsibilities in patent development, to bring the "byproduct" inventions arising from basic research to the point of practical application in order that the general public may benefit from the discovery. There will be some exceptions. Many inventions will turn out not to have commercial potential. There will be certain inventions which, by their nature, lend themselves to Government ownership and development. There will be some universities which, for valid policy reasons, do not elect to acquire rights to inventions. As a rule, however, it will be found that the university-contractor itself is the best available instrument for carrying inventions into the economy for the public benefit.

It is our impression that the policy framework provided in S. 1809 would permit Federal agencies to establish satisfactory arrangements with colleges and universities with respect to inventions related to Government-sponsored research. The bill also provides suitable arrangements for compulsory licensing if substantial efforts are not made to bring the invention to practice.

In view of the college and university dedication to the public interest, it will generally be desirable, although not essential, to establish patent rights in the university at the time of contracting rather than at the time of identification of individual inventions. At the time of contracting, the university's established policies with regard to patent responsibilities can be reviewed so that the sponsoring agency can determine their acceptability. Such policies would usually provide, on a uniform basis, a modest share of royalties to the inventor, thus recognizing the need for some incentive to identify inventions and provide subsequently the minimum necessary assistance. Such policies would also provide for nonexclusive licensing, but would recognize the need on occasion to provide exclusive licensing, subject to reasonable conditions as to period of exclusivity, if this were necessary to call forth risk capital.

Standards and criteria for university policies on the administration of inventions, governing the above points and other relevant features, are available for comparison and review. Furthermore, the respective Federal agencies already have accumulated experience in reviewing such policies. In time of peace, and also in time of war, it has been clearly demonstrated that the colleges and universities of the Nation are a vital national resource. Placing responsibility upon the universities for the development of inventions to the point of public availability offers, we believe, the best assurance that they will be developed. When there is royalty income from inventions, this would be plowed back to further strengthen these vital educational and research resources of the Nation, but this would occur only where the royalties, under suitable controls as to reasonableness, exceeded the cost of patent administration and prosecution of the unsuccessful, as well as the economically successful, ideas.

The Federal Inventions Act (S. 1809) provides general language in section 4(a) and 4(c) which would permit the sponsoring agency to assign invention rights to the university at the time of contracting, since each of these subparagraphs provides that the contractor may acquire greater rights at the time of conracting "in exceptional circumstances." The characteristic suitability of a university as an instrument of patent development might be construed to provide the exceptional circumstances necessary to warrant greater rights at the time of contracting. It is recommended, however, that this language be strengthened and made more specific by adding the phrase "or where the contractor is an educational institution" after the word "circumstances" on page 7, line 18, of the bill.

With respect to section 4(b) there does not appear to be adequate provision for the determination of the universities' rights in inventions at the time of contracting, and for this reason it is suggested that section 4(b) should be modified to include such a provision. This modification could be accomplished, for example, by inserting, "or educational" in line 5, page 8, following the word "commercial." Lines 2 through 5, page 8, if so amended, would read as follows "and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence directly relating to an area in which he had an established nongovernmental commercial or educational position, the agency" * * *."

The colleges and universities regard the broad and flexible approach proposed in S. 1809 as greatly preferable to a policy of assigning to the Government all rights to all inventions at the time of contracting. We believe that in many cases inventions would not reach the civilian economy if reliance were placed on a kind of mail-order catalog of available new product ideas. Frequently aggressive search is required to find someone willing to devote the energy and the additional capital to the task. The goals of the Government agencies and of the universities would seem to be identical—to make available to the public and to the economy the fruits of univeristy research, as quickly and inexpensively as possible. With such an identity of goals, the question would seem to be simply one of determining who best can take the initiative. We believe that, given the safeguards and controls we have suggested, the universities are best equipped to perform this function.

NICHOLS PRODUCTS CO.,
Moorestown, N.J., July 9, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Patents, Copyrights and Trademarks Subcommittee,
Senate Judiciary Committee,
Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: The action of your subcommittee in holding hearings during the past month in connection with various legislative proposals having to do with the American patent system has come to the attention of the American Society of Inventors. We feel that we have a substantial stake in the continuation of a strong and effective patent system, and would like to take this opportunity to express our views.

Much of the testimony presented before your subcommittee has been reviewed by us; and we feel that the statement presented by the national Small Business Association most nearly expresses the position of this organization. In essence, we favor the procedures prescribed by S. 1809 (McClellan bill) in determining the respective rights of the contractor and the Government in patents resulting from Government-sponsored research and development programs.

The position of the individual inventor would be substantially preserved and strengthened by the addition of various features of S. 789 (Saltonstall bill) as amendments to S. 1809. Specifically, we feel that section 9 of S. 789, which would allow the inventor whose patent has been infringed in connection with Government procurement, to obtain early and inexpensive remedy by administrative means, is urgently needed. Individual inventors cannot afford the expense and delay of seeking remedy by way of suit against the Government in the Court of Claims.

Section 11 of S. 789 would establish procedures and funds for the granting of awards to those whose inventions or discoveries were judged to be of outstanding merit. Various studies by the Department of Commerce and others have shown that the individual inventor is still a prolific source of important inventions and discoveries which contribute to the overall welfare. We believe that the recognition and rewards associated with an awards program would serve to stimulate creativity to the benefit of our national security and our society, and earnestly recommend that this provision of S. 789 be included in any overall patent legislation.

S. 1047 (Williams bill), like section 9 of S. 789, would substantially strengthen the position of the inventor patent holder in that he and/or his licensees would not find his patents infringed as a matter of normal routine by suppliers to the Government. The provisions of S. 1047, which allows for unlicensed manufacture upon certification by the Secretary of Defense, we feel, would alleviate the likelihood of unreasonable allegations and demands by patent holders. We believe that the Government of the United States has an ethical and moral responsibility to deal fairly and honestly with all its citizens; and that it should take the leadership in respecting the rights implicit in the patent grant. For these reasons we vigorously urge that the substance of S. 1047 be incorporated in any forthcoming patent legislation.

The American Society of Inventors appreciates the committee's courtesy in allowing it to submit these comments and respectfully requests that this statement is placed in the record of the hearings.

Very truly yours,

E. B. NICHOLS,
Legislative Committee, American Society of Inventors.

AMERICAN SOCIETY OF INVENTORS,
Whitefield, N.H., July 16, 1965.

DEAR MR. BRENNAN: Supplementing the statement of July 9 sent in by Mr. E. B. Nichols for our legislative committee, I am enclosing a proposed "Code of Creativity" for use by the Government agencies dealing with inventions. May I suggest that this be included in the transcript of the hearings following Mr. Nichols' statement, also the thoughts in this letter.

Our society would like to make a further suggestion that hearings be held on the problems of the inventor and creative scientist in dealing with the Government. These problems are more important than the problems of patents equities between industry and Government.

Thanking you for your cooperation in this matter, and the enclosed code will do much to improve the creativity and economic welfare of all concerned.

Respectfully submitted.

E. BURKE WILFORD, *President.*

CODE FOR CREATIVITY FOR GOVERNMENT AGENCIES

This code for creativity, designed primarily to give inventors and other creative scientists improved opportunity and incentive, will also promote progress in Government and industry. Economic growth and national defense will both benefit by revision of policies and methods for the purpose of encouraging creative workers and eliminating needless barriers in their paths.

1. The Government and industry can encourage economic growth by early recognition of inspirational ideas in the pioneering stages of development.

2. Analysis and recognition of the idea should include what is advantageous, as well as that which is not worked out and requires exploratory development. Direction of inventive thought into the right channels is very important.

3. The creator or inventor should be given a letter of status from the Government or development group about possibilities of production, so that he can develop solutions quickly and build a team or small organization. He should also not think too highly of his idea and work practically.

4. A portion of the expenses of every R. & D. contract or study should be used to have the inventor working with the development. If this is impossible, due to distance or personalities, the creative mind should make periodic visits to the development as a working consultant. Much leadtime is wasted by having the larger group in any development duplicate the work already done by the inventor and in some cases the development is spoiled by Government in-house development or a too long-haired approach.

5. If an idea is worthy of development, the inventor should be told when, how much, and at what point he can expect money from the R. & D. contract or a royalty on a test quantity. Waste of leadtime should be avoided in every stage of development.

6. Big and small industry working for the Government must be more receptive to the use of outside designs and systems, which are of a proprietary nature, and the status of the creative mind should be recognized when the development for production starts.

7. The patent and legal profession should see to it that all patent and proprietary data receive proper awards through administrative settlements, and Congress should provide a special fund out of which DOD can act quickly in these matters. Bureaucracy should treat the inventor with more personal attention, responsibility, and speed.

8. No patent legitimately issued and not assigned should be attacked by the Government lawyers on a basis of invalidity. If assigned, the inventor personally should share in the award and other solutions for blocks to inventions and adequate recognition of the inventors and creative scientists.

9. Nearly every country in the world has a more generous policy of pay for patents bearing on the national defense, and many countries have awards systems where the civilian and military personnel as well as the outstanding inventors and scientists receive reasonable sums of money to compensate them for their contributions beyond the call of duty. The U.S. Department of Defense has recommended that the Congress pass an awards bill patterned after the British system.

10. The Government should not hold any patents for contractors or Government employees except when they pay for the background work. Nonexclusive

licenses suffice and incentive to develop civilian uses is needed to inspire creativity for economic growth.

More liberal ways of dealing with inventors and creative scientists will be forthcoming by Government and industry through realistic code of creativity for R. & D. staffs of the Government. This will gradually cause industry to revise their thoughtless ways of treating inventors and bring better awards and royalty without so much legal delays and costs. Creativity will do more than any factor in raising the percentage of economic growth and is the best counter force to Parkinson's laws.

AMERICAN SOCIETY FOR PHARMACOLOGY
AND EXPERIMENTAL THERAPEUTICS, INC.,
Philadelphia, Pa., August 20, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The American Society for Pharmacology and Experimental Therapeutics is gravely concerned over the effects which pending legislation, in particular S. 1809, may have on research programs of university and other laboratories which are supported jointly by both governmental and nongovernmental funds. It is feared that unless the equities of all parties are properly recognized, the traditional collaboration of governmental, academic, and industrial organizations in research and development may be jeopardized, and progress for the benefit of the public thereby stifled. Accordingly, at the business meeting of our membership which was held at the University of Pennsylvania in Philadelphia on August 19, 1965, as a part of our fall meeting, the following resolution was passed which I was instructed to transmit to you:

"The free enterprise system, the source of many benefits to the public health, is based in part on the concepts of patent rights and of the exclusive control of an invention for a limited period. Legislation defining the assignment of inventions made in laboratories and by scientists enjoying support from public funds should preserve wisely the principle of patent protection. The rights of the public to benefit fully from the fruits of public research must be maintained without destroying the basis of collaboration between governmental, industrial, academic, foundation, and other laboratories on which scientific developments depend."

We should like to submit this resolution for the official record.

Thank you.

Respectfully,

GEORGE B. KOELLE, Ph. D., M.D.,
President.

AUTOMOBILE MANUFACTURERS ASSOCIATION, INC.,
Detroit, Mich., June 14, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The Patent Committee of the Automobile Manufacturers Association, Inc. appreciates this opportunity to express its views with regard to the Saltonstall bill S. 789, the McClellan bill, S. 1809, and the Long bill, S. 1899, all of which relate to Government patent policy.

After careful study of each of these legislative proposals, the members of the committee voted to endorse your bill S. 1809, in preference to S. 789, as representing the most reasonable approach to a solution to the problem of determining property rights as between the Government and its contractors in inventions made through the expenditure of public funds. The committee strongly opposed S. 1899.

In endorsing S. 1809, the committee requested that serious consideration be given to the following suggestions for amendment of the bill which they believe will benefit both Government and industry.

In section 3(a), to be consistent with the aforementioned definitions, it appears that the word "person" in line 16 should read "contractor". The latter

term as it is defined in section 2(d) includes the former and makes the language consistent with the newly added provision of section 3(b)(3) which assures a license to the contractor in any event and represents an important consideration.

As you are aware, American industry as a whole has not looked with favor on compulsory licensing such as is contemplated under section 3(b)(5). This provision could be rendered somewhat more palatable by the insertion in item (a) thereof of a minimum time interval, following the issuance of the patent such as 5 years, during which the patent owner could develop the invention to the point of practical application. This follows the existing philosophy of the NASA patent waiver regulations (title 14, pt. 1245, subpt. 1, Code of Federal Regulations).

The provisions of section 3(b)(8) for forfeiture of any rights where the contractor was found to have knowingly withheld a prompt and full disclosure are indefinite and susceptible of misconstruction. The terms "prompt and full" are subjective in the context used since ideas and innovations are intangible and not readily identified as to time of conception. Such time varies depending upon whether the bare idea or the practical embodiment of the idea is referred to for determination. Similarly, the requirement for a full description makes such requirement dependent on how far the idea has been carried to practical embodiment. It should be noted in this regard that the term "disclosure" has been defined in section 2 to cover a complete description, it being understood that this means such description to the extent available so that the contractor does not have to go out on his own to complete the description. Accordingly, it is urged that the reference to "prompt and full" be deleted from line 4 and from lines 12 and 13.

As regards the term "knowingly," this should be clarified to cover intent to avoid compliance with contract requirements. In the performance of any R. & D. contract, the contractor must always make a judgment as to whether an invention is reportable under the contract and when he does so in good faith on an informed basis, he is doing so knowingly. Accordingly, it is urged that line 12 be amended to insert" and in bad faith" after "knowingly".

Section 3(b)(9) would be more properly rewritten as a separate section in the bill since it would be unusual to require contract language interpreting the language of the act. It is also urged that the language be clarified to assert a positive prohibition against depriving the owner of background patent rights without compensation. The taking of such rights without compensation is considered to be inequitable and contrary to basic legal principles.

In section 4(a)(2), we again direct your attention to the practical impossibility to define or limit the application of the provision especially as it concerns the term "public welfare." It would be preferable to substitute for "welfare or safety" the phrase "safety or security and the inventions likely to result would be useful directly in such fields."

Since the final paragraph of section 4(a) in lines 18 to 22 inclusive on page 7 of the bill paraphrases section 1(a)(4)(ii) of the Presidential memorandum and statement of policy issued October 10, 1963, there appears to be no reason for omitting the additional provision of that policy. This can readily be achieved by the insertion of the following in line 22 of the bill:

"Greater rights may also be acquired by the contractor after the invention has been identified, where the invention when made in the course of or under the contract is not a primary object of the contract, provided the acquisition of such greater rights is consistent with the intent of this section 4(a) and is a necessary incenive to call forth private risk capital and expense to bring the invention to the point of practical application."

In section 4(b), lines 7 through 11 on page 8 of the bill, the head of the executive agency involved is given the right to take title to any invention made even though the invention does not come within the scope of whatever standards for taking title have been set up in section 4(a) upon a finding that "the public interest would suffer" if the contractor got title. Such a proviso is totally without reason and is considered to be entirely improper and unfair. Under such conditions, a potential contractor would have absolutely no basis for believing that he would under any circumstances be entitled to ownership of an invention made under a contract. Personalities and politics would have full reign under such a legislative device.

The committee recommends that lines 7 through 11 on page 8 in section 4(b) be deleted without substitution. This revision would also require that the

reference to section 4(b) in line 14 on page 9 under section 5(a) (1) should likewise be stricken.

To insure that any patent application filed by an agency head may be properly identified, it should be filed in the name of the inventor or inventors. This necessitates the insertion of the phrase "in the name of the inventor or inventors" in section 7 at line 21, page 13, after "invention" and in section 8(a) at line 18, page 14, after "application."

It is further recommended that the last two sentences in section 8(a) beginning in line 23 on page 14 and all of section 8(b) be deleted in their entirety. It has ever been the philosophy of Government since the report and recommendations of the Attorney General to the President by Attorney General Tom C. Clark in 1947 that the public interest would best be served by opening Government-owned inventions to the general public and that licensing of such inventions for a royalty is not only difficult and likely to be inequitable but would necessitate detecting and prosecuting infringers.

To the end that this bill would comply with the foregoing recommendations of the Attorney General, section 8(b) should be changed by the entire deletion of its present text in lines 3 to 11 on page 15 and substituting "Every citizen of the United States shall have a free right to practice the invention covered by any patent to which the U.S. Government acquires title."

The members of the AMA Patent Committee desire to commend your efforts in presenting the bill, S. 1809, and specifically oppose the Long bill, S. 1899.

Respectfully submitted.

WILLIAM L. SCHERER,
Secretary, Patent Committee.

STATEMENT BY ANDREW J. BIEMILLER, DIRECTOR, DEPARTMENT OF LEGISLATION, AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

Mr. Chairman, my name is Andrew J. Biemiller. I am director of the Department of Legislation of the American Federation of Labor and Congress of Industrial Organizations. I appreciate this opportunity to set forth our position on legislation to clarify the patent policies of the U.S. Government.

The basic principle which is the foundation of the AFL–CIO concern with the patent policies of the Federal Government is that all patents developed with public funds should be in the public domain.

At present, this general principle is followed by most Federal agencies. With the major exceptions of Department of Defense contracts and National Aeronautics and Space Agency contracts, any patent issued on inventions made by a contractor with a Federal agency is issued to the U.S. Government. The contractor receives a nonexclusive, royalty-free license, and the patent is available for use by other firms through cross-licensing procedures.

Federal Government expenditures in research and development have risen over the past 10 years from about $3 billion to $15 billion. This outlay is not likely to get any smaller in the foreseeable future and, indeed, is likely to rise still further. The Department of Defense is now spending R. & D. money at the rate of about $7½ billion a year, and NASA alone hands out some $4 billion to $5 billion a year in R. & D. funds.

The Federal Government spends at least two-thirds of the Nation's R. & D. money, and about 60 percent of these public funds go to 10 giant private corporations. The U.S. Government has made an enormous investment in research and development in defense and nondefense activities.

Invention has become big business. The lonely inventor in his own private workshop is the exception today. Seventy percent of all patents are issued to corporations.

Clearly there is a big public interest in the spending of public funds which bring profits and progress to private business. Furthermore, there is a serious danger that public funds will subsidize private monopoly. This will occur if the giant corporations hold exclusive patents on federally subsidized inventions. We oppose the use of public money to strengthen private monopoly.

In 1947, Supreme Court Justice Tom Clark, then Attorney General of the United States issued a report containing this statement on the issue before this committee:

"When patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest re-

quires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform the research work; will avoid undue concentration of economic power in the hands of a few large corporations, will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free, competitive enterprise."

We agree with this view, and we urge this subcommittee and this Congress to take the same enlightened view of the public interest in patent policy.

We see a basic inconsistency in efforts of giant corporations in support of Federal patent legislation that would make it difficult, if not impossible, for a Federal agency to establish Federal ownership of federally subsidized inventions. These corporations are asking for a privilege which most do not grant to their own employees. Individual inventors employed by such corporations do not acquire patent rights to their inventions. The patent rights pass to the employing corporation.

We do not bring to this subcommittee detailed expertise in the complex field of patent law and regulation. But we are convinced that any fair and reasonable view of the public interest will suggest that all patents developed by private business with Federal funds should be turned over into the public domain.

With this general principle in mind, we endorse S. 1899, sponsored by Senator Long of Louisiana. Senator Long's bill would accomplish the objective we seek in Federal patent policy, and we urge this subcommittee to approve S. 1899.

Mr. Chairman, I appreciate this opportunity to present the views of the AFL–CIO.

Thank you.

U.S. SENATE,
June 7, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR JOHN: I understand that at your recent hearings on patent practices a statement was introduced into the record of the subcommittee which dealt with the pricing practices of the Ames Co., a subsidiary of Miles Laboratories, Inc., of Elkhart, Ind. In this statement the Ames Co. had been criticized for the price charged for a test kit developed to test for phenylketonuria.

I found that there were several errors contained in that statement when it was originally made on the floor on June 3, 1965, and I made a statement on the floor of the Senate which attempted to set the record straight as far as Ames' pricing was concerned.

I ask that my statement, a copy of which is attached, be included in the record of your subcommittee at an appropriate place.

With best regards.

Sincerely,

BIRCH BAYH.

[From the Congressional Record, June 3, 1965]

BLOOD TEST KIT FOR PHENYLKETONURIA (PKU)

Mr. BAYH. Mr. President, recently, on the floor of the Senate, reference was made to the development of a blood test kit for phenylketonuria—known by some of us who are less articulate and knowledgeable in the field of medical science as PKU—which has been marketed by Ames Co., a subsidiary of Miles Laboratories, Inc., a well-known 80-year-old Elkhart, Ind., pharmaceutical manufacturer. This blood test promises to save thousands of infants from mental retardation and, when broadly accepted, will be a remarkable advance in medicine.

I should have prefaced my remarks, when I referred to those of us who are less knowledgeable in the field of medical science, by excluding the present Presiding Officer, the Senator from New York (Mr. Kennedy) because I know of his long interest in the field of mental retardation and mental health.

This test method was conceived by Dr. Robert Guthrie, of Buffalo, N.Y. In performing the test a drop of the infant's blood is used to determine if the child is afflicted with PKU. If undetected and untreated, brain damage occurs with

subsequent mental retardation; however, early detection and medically supervised dietary treatment prevent severe mental retardation in most phenylketonuric infants. Such test procedures hold forth a promise of normal, happy lives.

The Ames Co. undertook the development of the Guthrie test method and has marketed a technically refined product.

The discussion on the Senate floor was based on certain data supplied by the Public Health Service and the Children's Bureau of the Department of Health, Education, and Welfare. There were certain inaccuracies in this data which should be corrected for the record.

To set forth the general position of Ames, I would like at this point to quote from a letter to the shareholders signed by Walter A. Compton, M.D., president of Miles Laboratories, Inc.:

"Our Ames Co. has been involved in PKU research for nearly 10 years. In 1958 it pioneered in developing and bringing to market a urine test to detect this condition, and has in intervening years very materially increased knowledge and attention to this preventable mental disease throughout the world. While not an important product in terms of sales volume, this test has performed a significant role in medicine since, if used routinely, it could lead to the substantial improvement, perhaps even virtual elimination, of PKU as one of the causes of mental retardation.

"It was because of Ames' reputation in this field that a Dr. Robert Guthrie brought his test concept to us. This test is done on blood and, although much more difficult and expensive to perform, it may have the advantage of detecting PKU a few days earlier than can a urine test. Ames agreed to manufacture and market a test based on the Guthrie concept and began to do so in the fall of 1963. This proved to be quite an undertaking because a great deal of research time was spent in refining the test to meet essential standards of quality and uniformity. Ten substantial technical alterations and improvements were required before in our judgment the test could be said to be sufficiently reliable for general use. Moreover, a new production facility has been built and equipped to manufacture the test properly because of special requirements inherent in the product. After this, an intensive educational campaign was necessary to get the new product brought to the attention of health authorities and into clinical use; this was a costly undertaking.

"Ames has never had any monopoly position in the market; there are several competing products that we know of. Nor has Ames even approached recovery of its investment in making this product available. The new product was originally scaled from our estimates to be sold at a price resulting in 42 cents per test. After some 5 months of manufacturing and marketing experience, this was reduced to the present level of approximately 21 cents. At this price, if it were possible for every child born in the United States each year to be tested, this would amount to about $850,000. Yet it has been estimated that early detection and the avoidance of institutional care would save the taxpayers $20 million when spread over the lifetime of the PKU victims born each year. This is quite apart from the human misery which would be prevented.

"In summary we believe that your company has acted in the public interest by developing, manufacturing, and bringing into use reliable tests produced under the high standards of quality required for such products. Actually, this test based on the Guthrie concept was made available largely as a public service, without expectation of significant profit, as part of our responsibility as a leader in this field of medicine. We believe it has made a worthwhile contribution. Much more could be said about the inaccurate inferences which have been drawn in the press in this matter but we believe the above represent the responsible and significant facts."

Now let me set forth for the record the points in conflict and in more detail explain the position of Ames.

It has been implied that, by reason of the fact that Dr. Guthrie filed a patent application covering this test method and thereafter entered into a license agreement with Ames, this action resulted in delaying disclosure of the Guthrie test method. This is clearly erroneous. Dr. Guthrie had discussed his test method in public as early as July 1960 at a scientific meeting in London and further publication in U.S. medical journals followed in 1961. Thus Dr. Guthrie's invention was not concealed and was public knowledge almost 2 years prior to the April 1962 filing of a patent application by Dr. Guthrie, and long prior to the

June 1962 agreement with Ames Co. for the development and marketing of the blood test.

It has been implied that the Ames Co. or Dr. Guthrie sought to establish rights in the Guthrie test method contrary to the Government's rights.

If this were the case, I would be highly alarmed. However, the facts are to the contrary. At all times Ames Co. and Dr. Guthrie and his private sponsors recognized that any agreement was subject to the assertion of controlling Government rights. The June 1962 agreement between Ames Co. and Dr. Guthrie was expressly subject to the prior rights of the Government.

I have had an opportunity to read verbatim the contractual agreements. One clause specifically requires that Government laws are controlling and recognized.

Moreover, the suggestion that Ames and Dr. Guthrie were acting independently of the Government's interest ignores the plain fact that—as recognized in the provision that the agreement was subject to the assertion of Government rights—the Surgeon General had the power to review and approve any license agreement and to impose such additional conditions as he believed necessary for the public interest.

(At this point Mr. Young of Ohio took the chair as Presiding Officer.)

Mr. BAYH. Mr. President, yesterday, we had a rather lengthy and, I felt, enlightening debate on the various aspects of our patent law, especially in the field of medicine and health. The Surgeon General has the power of review and approval and has used it extensively. He used it to deny the application in this particular case.

Although the terms or conditions for a license were never resolved, since no license was granted, advisers to the Surgeon General had indicated that if any license agreement were approved, it would be limited to a maximum duration of 2 years and would embody other specific limitations or conditions.

As matters developed, in May of 1964 the Surgeon General—again within his authority—disallowed the granting of any form of exclusive license. In short, Ames has never had an exclusive license, and Dr. Guthrie has assigned his patent application to the Government.

Even though Ames received no exclusive rights for even a limited period, it has continued to serve the public interest by making available a fully developed blood test kit and has by extensive informational efforts directed to the professions emphasized the value of PKU testing.

In this connection, it has also been suggested that the blood test kit originally made by Dr. Guthrie had already been developed and tried, and that further development was unnecessary. This is not true. That product was at best an experimental product for field trial use only.

The product marketed by Ames Co. is not the same product as produced for the field trial. Ames Co. has spent $93,000 in research and development on the product, and a number of significant changes were required to be made in order to produce a marketable product.

While certainly a contribution, it must be recognized that the test product that was being produced by Dr. Guthrie for field trial was being made under relatively rudimentary conditions in a rented house and with only limited facilities available to him. Dr. Guthrie contacted the Ames Co. because he recognized that the product had to be developed and brought out under the direction of a modern pharmaceutical company that had experience and broad skills and facilities available to it, since he knew that Ames Co. had experience in just that kind of testing. Also, it was demonstrated at the time that there were defects in the test, and that further development and refinement of the product was essential before use by the public in general.

Products to aid in the diagnosis of disease require as high an order of assurance as possible that the test results will be accurate. The danger lies, study shows, between false positives on the one hand and false negatives on the other hand. A false positive would cause undue apprehension, although the baby would always be rechecked and the fact that it was a false positive would be confirmed with no harm done. But a false negative—indicating that the disease was not present—could be tragic. This is particularly true in the case of tests for PKU since, if undetected and untreated, the result may and probably will be irremediable brain damage. This is so since corrective clinical treatment must be taken as soon after birth as possible, if the desired results are to be obtained.

A private company cannot distribute a diagnostic test product for public use until all known defects are removed and there is an assurance of reproductibility

of results and accuracy of performance. This care must be exercised not only for reasons of integrity, but also to fulfill adherence to Government regulations and to minimize exposure to civil liabilities. Ames Co. devoted considerable resources and scientific technology in order to develop a marketable product.

Let me specify the additional steps taken by Ames to improve the product to make it marketable, to make it a product of integrity and reliability, and to show that a great deal of effort was required from the time of final testing to the time of selling it over the counter to the public in general.

First. The micro-organism *B. subtilis* ATCC 6051 was changed to *B. subtilis* ATCC 6633 for better standardization. This was necessary because ATCC 6633 was readily available from reputable commercial sources while ATCC 6051 was not. There were available exacting control standards for ATCC 6633 which were not defined for the ATCC 6051 strain of the *B. subtilis* used in the original kit.

Second. The heat dried spore suspension in the original kit was changed to a liquid suspension in a sealed ampule. It was necessary to make this change to secure standardization and to have a reliable means of securing an exact range of viable spores. This could not be accomplished by the original method of heat drying.

The possibility of contamination strongly existed in the original method as spore vials were open to the atmosphere during the required drying procedure. The sealed ampule provided maximum accuracy as to spore addition to the test medium.

Third. Since heat drying was eliminated, the total spore count per ampule was decreased. This refinement was based upon considerable Ames research effort to arrive at a definite spore count per ampule which would result in optimum readability of the test.

Fourth. The glucose content was decreased from 1 to 0.5 percent. The reason for this change—although it appears to be relatively insignificant—nevertheless was to improve the stability of the end product in terms of assuring maximum lifespan from date of manufacture to date of use.

Fifth. Ferric chloride was eliminated to prevent turbidity in the final dissolved medium. This improvement again resulted in increased readability of the test medium, an important attribute of such test.

Sixth. Sodium sulfite as used in the original kit was changed to sodium sulfate in the refinement process to be in keeping with the growth medium described in the Demain study "Minimal Media for Quantitative Studies with *Bacillus Subtilis*," an established reference on the subject to make it uniform to other tests which are conducted throughout the country on other products.

Seventh. The dehydrated medium produced at Ames' direction by an independent source was a definite improvement over the original process. The original method utilized a dry blend of ingredients which was found unsatisfactory in that total drying was difficult to obtain and the method called for numerous stages of mixing and dispensing. This, in turn, required a constant checking of each mixture as it was completed. In changing to the dehydrated medium, Ames was able to achieve definite uniformity of component ingredients, minimize contamination exposure, increase stability, and meet commercial production requirements. This refinement also made the test easier to perform and lessened the possibility of error by the user.

Eighth. Ames' refinement process eliminated the separate vial of dried b-2-thienylalanin used in the original kit. Ames incorporated the b-2-thienylalanin directly into the dehydrated medium. A decrease in concentration of B-2-thianaylalanin was found to be necessary to secure an optimum medium. These changes were pointed toward the good manufacturing objective of securing maximum uniformity of essential ingredients by combining three of the original components into one dehydrated powder and thereafter into one container as opposed to three separate containers originally utilized in the kit. It makes the kit easier to use and more reliable.

Ninth. An additional improvement was the utilization of five plastic trays and covers in each of the Ames kits as opposed to but one plastic tray and cover in every fifth original kit. Ames found it necessary to provide a one-time use tray. The single tray and cover per every fifth kit as originally devised required using the single tray for repeated testing, thus increasing contamination exposure. Evidence of such contamination had been observed in the single tray method.

Tenth. In addition to the refinements set forth above, considerable time and effort were expended in developing quality control procedures and specifications to insure that the product as manufactured in individual batches and from batch to batch would be accurate and effective in testing babies. A few of such specifications and procedures are—raw material testing, moisture control of test medium, identity control procedures, microbiological assay on *B. subtilis* spores, procedures for stability testing of batch file samples at 6-, 12-, 24-, and 36-month intervals ,and finished product testing procedure.

Mr. President, the development and marketing of a product of the nature of Guthrie product is an intricate process. We are dealing with the lives of young babies, just born, and it is important that we go to the *n*th degree to protect their health and safety.

All of this work on the inhibition assay involved substantial use of research personnel and considerable product development, including experimental manufacturing. The Ames quality control methods development group worked out assay procedures for phenylalanin, B–2 thienylalanin, and medium components; this has been expressly commented upon in item 10 above. The microbiology section and the biostatistical section of Ames quality control developed an evaluation method for kit performance which resulted in a consistent procedure for determination of acceptability of the finished kit. This technological accomplishment was once again in addition to the other quality control procedures set forth in item 10 above.

The above summary refutes a charge that no further development was necessary to market the product commercially. This development effort required additional effort, investment, and expense.

Mr. President, there has been a considerable amount of discussion in committee and on the floor of the Senate during the past several months about some unfortunate practices indulged in by certain drug companies. I do not condone them. I do not condone the charging of exorbitant prices. Ames Co. has been accused of charging an exorbitant price for the product that it developed from the Guthrie test method and it has been stated that such product could be produced for $6, including all costs, for a kit containing 500 tests. At the $6 figure, the cost per test would be 1.2 cents per test. Dr. Guthrie had been working under Federal grants for several years during the development of his blood test method. He had received Public Health Service support of more than $250,000 and had received additional outside private support of about $100,000.

In 1962 the Children's Bureau made a grant for Dr. Guthrie to carry out a broad-scale program of field trial of this blood test method. During this project $570,207 was spent by the Children's Bureau to test 404,568 babies across the country. A breakdown of the budget for this project shows the following:

Expenditures of Children's Bureau grants-in-aid funds (title V, pt. 1, Social Security Act) for Guthrie PKU project, fiscal years 1962–64

Special project grant to University of Buffalo (Dr. Guthrie):	
Staff	$120,132
Supporting services (travel, laboratory supplies, epidemiologic surveillance, postage, etc.)	109,864
Test kit materials	61,467
Scientific equipment	3,444
Total	294,907
Cost of PKU field testing by 30 States (formula grant funds under title V, pt. 1, Social Security Act)	275,300
Total	570,207

This table shows the errors in the statistics of the Children's Bureau as to what the product cost to make. I call particular attention to the cost of the test kit materials of $61,467.

Although in several instances the Federal agencies suggest that the cost per test of the Guthrie kit was 1.2 cents per test, this is clearly erroneous. The budget supplied by the Children's Bureau indicates that the actual cost of the test kit materials alone was 9.2 cents per test based on the number of

blood and urine tests—665,902—actually performed during the program. It should be noted that this is for materials cost only and does not include other costs attributable to manufacturing and distribution since it ascribes no labor or overhead. These costs are not defined in the Children's Bureau budget.

Only the cost of the test material is included, and even so the cost was several times the amount of the reliable cost.

It is impossible to determine what the actual cost per test was during the Children's Bureau program. However, it can be conclusively proven that the per test cost was more than 9.2 cents and not the 1.2 cents per test as indicated in the agency statements.

But regardless of what the costs may or may not be for a governmental agency engaged in manufacturing diagnostic products, the pertinent question is what are the costs—and resulting price—of a reputable, experienced private company that must assume all legal responsibility for and stand behind its products. Further, it is impractical to compare the cost or price of the original field trial test unit with that of the Ames product. It would be similar to comparing a model T Ford to a 1965 Lincoln. Although both are for the same function, the model T is obviously a rudimentary form of transportation and the Lincoln is a very sophisticated, highly refined product.

It is important that misconceptions concerning the price of the Ames product be corrected. It is suggested in certain memorandums by the Children's Bureau that the marketed price of the Ames Co. for the Guthrie test kit was $262.50 for 500 tests or more than 52 cents per test. This is inaccurate. The test kit produced by Ames has never been priced at $262.50, nor has it ever been produced in units of 500.

I do not know where this information was obtained. It is wrong. It is erroneous. It is false. In fact, the test kit has been produced only in units of 325 since the inception of its marketing by the Ames Co. The price per test of the Ames kit was 42 cents per test from November 1963 until April 1964. At that time the price was cut to 21 cents per test.

The misconceptions concerning Ames selling price imply an unconscionable profit. This also is wrong.

In this connection I ask unanimous consent to have printed in the Record at this point a memorandum from the vice president of finance for Miles Laboratories, Inc., to the president of Ames Co., Mr. George Orr, concerning a cost analysis made of the Ames Co. PKU blood test kits. I also ask unanimous consent to have printed in the Record at this point—and this is of equal importance—a copy of the examination made by the public accounting firm of Price Waterhouse & Co.

There being no objection, the material was ordered to be printed in the Record, as follows:

"MILES LABORATORIES, INC., INTEROFFICE COMMUNICATION,
"May 25, 1965.

"To: George W. Orr.
"From: Joseph H. Hoyt.
"Subject: Ames PKU blood test kits.

"In accordance with your request I have received our sales and cost records in regard to subject product.

"In my opinion, the accompanying statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits presents fairly the data shown therein.

"The unrecovered cost to date of $131,823 does not include the cost of $50,000 for the film, 'PKU Mental Deficiency Can Be Prevented,' nor does it include an allocation for corporate overhead expense, such as executive, legal, financial, or administrative. These items have been excluded because it is felt they may be controversial.

"The records show that our current selling price for the Ames PKU blood test kit is 20.8 cents per test and that our direct production and distribution costs are 6.6 cents per test. However, after making allowance for continuing marketing, research, and divisional administrative expenses, I estimate our total operating cost at 17.4 cents per test. This leaves an operating margin of approximately 3.4 cents per test.

"If Ames is able to sell tests for 20 percent of the total U.S. potential market of 4 million babies, this would produce annual operating margin of some $27,000.

At this rate, assuming no further reduction in prices, it will take about 5 years to recover those costs yet unrecovered at April 30, 1965.

"Prior to April 1964 our selling price was 41.7 cents per test. However, at that time our production and distribution costs alone were 15.1 cents per test. This higher cost was due to heavy quality control charges and other increased expenses attributable to the learning period.

"JOSEPH H. HOYT.

"*Miles Laboratories, Inc.—Statement of unrecovered costs at Apr. 30, 1965, on Ames PKU blood test kits*

"Net sales of test kits from Nov. 1, 1963 to Apr. 30, 1965	$72,243
Costs and expenses applicable to these sales:	
Production	24,380
Distribution [1]	4,141
Advertising	29,025
Selling [1]	22,215
Division Administration [1]	3,589
Total	83,350
Excess of costs and expenses	11,107
Add:	
Cost of research and development commencing in 1962	93,753
Cost of special equipment and facilities	26,963
Total unrecovered costs at Apr. 30, 1965	131,823

[1] Represents division expenses basically allocated as a percentage to net sales. No amounts are included for corporate administrative overhead expenses of Miles Laboratories, Inc.

"CHICAGO, ILL., *May 26, 1965.*

"The BOARD OF DIRECTORS,
"*Miles Laboratories, Inc.,*
"*Elkhart, Ind.*

"DEAR SIRS: We have examined the consolidated financial statements of Miles Laboratories, Inc., and its subsidiaries for the years ended December 31, 1962, 1963, and 1964, and have previously expressed our opinion thereon under dates of February 11, 1963, February 17, 1964, and February 19, 1965. Our examinations were made in accordance wtih generally accepted auditing standards and accordingly included such tests of the accounting records and such other auditing procedures as we considered necessary in the circumstances.

"As a supplement to the foregoing examinations, we have examined the statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits and made such additional tests of the pertinent accounting records and performed such other auditing procedures as we considered necessary in the circumstances. In our opinion, the accompanying statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits presents fairly the data shown therein.

"Yours very truly,

"PRICE WATERHOUSE CO."

Mr. BAYH. It will be seen that the public accounting firm report supports the analysis.

This memorandum indicates that the total operating costs are 17.4 cents per test leaving a margin of approximately 3.4 cents per test. Against this the Ames Co. is trying to recover costs which to April 30, 1965, were yet unrecovered in the amount of $131,823. The unrecovered costs were largely involved in the research and the development of the product and acquiring special equipment and facilities required for the manufacture of these test kits.

There is a very small potential market for the product, one in which there is little volume and very little hope of profitability. Further, in the highly scientifically oriented pharmaceutical industry there is also the problem of product obsolescence because of new research and technical achievement. Research is now being conducted by other companies in this very area of medicine.

One product is being tested now, which, if it proves to be successful, could make obsolete the Ames product and the product of its competitors.

Therefore it is impossible to project the length of time that the Ames test will be used. It is difficult, then, to insure recovery of the unrecovered costs to date. I do not believe that the present cost is providing an unconscionable profit.

In keeping with its responsibility, Ames Co., has undertaken an extensive program of education concerning this form of mental retardation, and the use of its product for the detection of this condition. Such costs are a part of business operations and must be assigned to the products involved. These costs include such items as medical literature, informative mailings, and scientific exhibits. In this particular case Ames Co., is not assigning to this product certain other educational costs which could be attributed to it.

An example of the latter is the sound motion picture entitled "PKU—Mental Deficiency Can Be Prevented." Ames underwrote the production of this film, which was produced under the direction of and narrated by Harry A. Waisman, Ph. D., M.D., professor of pediatrics, University of Wisconsin Medical School. Fifty prints of this film have been made for Ames' film library. There are an average of 65 to 70 showings per month, and it is estimated that the film has been viewed by well over 100,000 persons. The film is shown to medical, nursing, and medical technician students; hospital medical and nursing staffs; medical, nursing, and medical technician society meetings; and even to college and high school science students. Several State public health agencies have purchased prints of the film—at cost of the print—for their film libraries.

I had the good fortune to see the film. I believe that most Senators would recognize the importance of striking out as forcefully as we can in every way possible to prevent mental illness and mental retardation. If it were possible, we should offer to Ames a type of "Emmy" award for the fine production and the public service that is being rendered by the film.

In summary, an analysis of the expenses for the Ames blood test kit will show that the price is in keeping with good business practices and well within reason. The product is being marketed by Ames Co., at a reasonable price.

Our Nation is becoming increasingly aware of the serious effects of mental illness. Millions of dollars are spent annually in an effort to cure those who are afflicted. In fact, this Congress has recently embarked upon a program which will result in investing significantly higher proportions of our national resources into curing and caring for those who are mentally ill.

Fortunately for our country, men and women of science and medicine in both industry and academic life have recognized the need to do battle against mental illness long before the majority of us in the Halls of Government. Because of their leadership, significant technological accomplishments have been made not only to treat mental illness after it has been diagnosed but to prevent the very occurrence of the disease.

Dr. Robert Guthrie has been one of the academic contributors. He has conceived a test which will help make it possible to save several hundred American babies, boys and girls, and eventually men and women, from being afflicted with mental retardation each year. How much wiser it is to devote resources to try to prevent an illness from occurring than to be faced with the alternative of spending many times this amount of funds and effort for treatment.

Ames Co. industrial scientists had developed a urine test to detect PKU before the development of the Guthrie blood test. Ames urine test, although it may have the disadvantage of detecting PKU a few days later than the Guthrie blood test, continues to be used and has made a continuing significant contribution to medical science. Because of the effort devoted to the cause of mental retardation prevention by Ames Co., many young Americans are whole and happy instead of facing a life-long tragedy of retardation. I, for one, think that Dr. Guthrie and Ames Co. should be complimented for the effort they have made for the development of effective blood tests against PKU and for the effort Ames Co. has made to make this product readily available to members of the medical profession.

We in the Congress and in the State legislatures recognize our responsibility to enact programs which devote more of our resources to an attack against the dreaded mental diseases which are rampant throughout the country. But I believe that we must also recognize that mental illness can be arrested only with the full cooperation of government, industry, scientists, and educational institutions.

I make that statement on the floor of the Senate and take the time of Senators only because I believe it is important that when we make accusations which tend to make such cooperative ventures between medicine, government and educational institutions less than desirable, we are in fact not serving the purpose which we all really wish to serve; namely, rapid elimination of mental illness wherever it may appear and in whatever form it may appear.

BELL TELEPHONE LABORATORIES, INC.,
Murray Hill, N.J., May 24, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights, Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: This is in response to your invitation at the time of introduction of S. 1809, a bill to establish a uniform national policy concerning property rights and inventions, to communicate comments and any proposed amendments to the bill.

We support the bill as a reasonable and balanced approach to the basic question of "title versus license" which underlies the establishment of any uniform Government patent policy.

The following clarifying amendments are proposed for the reasons noted in the comments appended. These amendments do not affect the design of the bill nor do they result in changes in the underlying policies.

Page 3, section 3(b)(1), line 24, change "the prompt and full disclosure" to "a prompt disclosure".

Comment.—This conforms the use of the term "disclosure" in CONTRACT REQUIREMENTS with its definition in section 2(f).

Page 4, section 3(b)(3), line 13, after "license" insert "shall include the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded and".

Comment.—This will avoid placing the contractor in a position of inconsistent contractual obligations. The inserted language has been adopted from NASA's waiver regulations where it has been employed since 1962.

Section 3(b)(3), line 15, after "part" insert a period, strike "and" and insert "Such license and right".

Comment.—This is an editorial modification necessitated by the next previous amendment.

Page 5, section 3(b)(5), line 7, in subsection (a), after "has not" insert "within three years after a United States patent issues on such invention".

Comment.—It would seem that a contractor should have a reasonable time within which to demonstrate efforts to bring the invention to the point of practical application. The 3-year period is the same as that employed in the Presidential memorandum.

Page 5, section 3(b)(5), line 9, in subsection (a) after "practical application" insert "or has made the invention available for licensing royalty-free or on terms that are reasonable in the circumstances".

Comment.—This suggested amendment has also been adopted from the Presidential memorandum. A compulsory license would appear unnecessary if the invention is already available either royalty-free or on reasonable terms.

Page 5, section 3(b)(6), line 16, after "may" insert "timely."

Comment.—Since time is of the essence in preserving foreign rights, it appears desirable to allude to this factor.

Page 6, section 3(b)(8), line 4, after "prompt" strike "and full."

Comment.—See comment above with respect to amendment to section 3(b)(1).

Page 15, section 8(b), line 6, after "granted" (second sentence), cancel "under" and insert "subject to the license reserved to the contractor by section 3(b)(3) and," after "such" insert "other."

Comment.—This insures that the license reserved to the contractor is retained despite the designation of the license in the preceding sentence as "exclusive."

We appreciate the opportunity to comment on your bill and we favor its adoption over the other patent policy bills pending before your subcommittee.

Very truly yours,

E. W. ADAMS, Jr., *Patent Attorney.*

NEW HAVEN, CONN., *May 26, 1965.*

Hon. JOHN L. MCCLELLAN,
Senate Office Building,
Washington, D.C.

DEAR SIR: Pursuant to your letter of April 30, 1965, I, as a member of the patent bar, have taken some interest in the current situation which has developed in connection with the Government patent policy. In particular, I refer to S. 1809, S. 1899, and S. 789.

Upon careful review of these bills, I would say that the S. 1899 approach of Senator Long is neither practicable nor acceptable. It misinterprets the purpose of the President's statement on patent policy and creates a situation which is not in the best interests of the public or the contractors. In contrast to Senator Long's bill, Senator Saltonstall's bill includes various and sundry matters, i.e., inventive contributions and awards therefor, amendment to 28 U.S.C., section 1498, etc. In these respects it requires some reflection and perhaps some investigation by the Presidential Commission in order to develop sufficient information as to the necessity for making such changes.

This leaves, for the most part, your own bill, sir, S. 1809, as the bill which should be given careful and most serious consideration by the Congress at this time. However, this bill does require at least some minor changes, primarily centering about the implementation of the Government patent policy, so as to fully develop the benefits to the public as a result of the vesting of the title in the Government. Accordingly, after careful consideration, I should like to suggest the following amendments to your particular bill. I believe these amendments would strengthen the bill.

Page 5, section 3(b)(6), amend to read as follows:

"(6) provide in the event the principal or exclusive rights in any invention are acquired by the head of the agency, on behalf of the United States, and such agency head does not actually file a patent application in order to secure a patent in the United States or in any foreign country before a predetermined time, said predetermined time not being greater than nine months from the date of disclosure of the invention to the agency and in any event not less than three months before the statutory bar date, appropriate means whereby the principal rights in the invention will automatically revest in the contractor if either (a) notice is not given by the agency head to the contractor that a patent application has actually been filed within the above-mentioned predetermined time, or (b) the agency head notifies the contractor that he does not elect to file a patent application in the United States or in any foreign countries before the predetermined time mentioned above, subject to the rights reserved to the United States in subsection (b)(2) of this section;"

Page 8, section 4(b), line 7, after "he determines" add "not later than six months".

Page 8, section 4(b), line 11, add the following sentence: "The agency shall reimburse the contractor for the reasonable expenses encountered in filing a patent application or in prosecution of a patent application in any case where the agency decides to take greater than a nonexclusive license."

Page 15, section 8(a), line 10, after "may be granted" add "only"; after "with" delete "or without."

Page 15, section 8(a), line 11, after "the United States" add: "each agency is required to institute appropriate judicial proceedings to enforce the principal ownership rights of the United States in order to prevent others from using its patents without the payment of appropriate royalties."

In particular, I propose that section 3(b)(6) be amended to provide that if the Government takes title to an invention and does not actually file a patent application within a predetermined time limit, the contractor then be granted the right to regain the title and be permitted to file a patent application, subject, naturally, to the rights reserved to the United States in section (b)(2) of section 3, so that protection will not be lost to both the contractor and the U.S. Government. As section 3(b)(6) is currently written, there are no provisions which make it necessary for the Government to actually file a patent application (assuming the invention is patentable) unless it so desires. If the Government does not file a patent application, then the contractor is not getting what he is supposed to get under section (b)(3) (that is, an irrevocable

nonexclusive royalty-free license for the practice of the invention throughout the world).

If the Government does not file and the contractor cannot file because he does not have title, it is conceivable that someone, at a later time, could file an application covering the same invention and thereby prevent either the Government or the contractor from using the invention. Additionally, there is no justification for allowing the Government to permit inventions to be kept secret or become abandoned or disregarded due to (1) a statutory bar because they have not filed in time, (2) the administration feeling that they have not sufficient funds to file patent applications, or (3) the administration not desiring to file patent applications on selected inventions, unless the contractor is given an opportunity to at least attempt to protect the invention. In substance, in the present clause (6) of section 3(b), you have attempted to accomplish this purpose with regard to foreign rights. It is believed it should be extended to the rights in the United States so that protection will not be lost to the public in general.

With further regard to the present bill, section (6), if the United States did not file an application and the contractor could not file an application, foreign competition could enter into the U.S. market even though the U.S. Government was the first to own the subject invention and could have filed a patent application. This is an additional basis for my belief that the contractor should be given the chance to file in the event the Government does not file a patent application in the United States. Accordingly, amendment of section 3(b)(6) as suggested, should be considered in order to fully protect the Government, the contractor, and the public of the United States.

Additionally, I propose that section 4(b) be amended to place a time limit on the retaking of greater rights than a nonexclusive license where the administrator or agency head believes that public interests would suffer as a result of the contractor retaining the principal exclusive rights in the invention. It is unjust to retake title from the contractor after he has filed a patent application and invested capital for a period of years to exploit the invention. Further, if this occurs, contractors will be deterred from making capital investments until the rights are firmly established. By placing a limitation, such as 6 months, definiteness would prevail and the contractor could then make his plans for exploitation of any and all inventions on which he has, initially, more than a nonexclusive license.

With further regard to section 4(b), I propose that, in all fairness, if the contractor initially files a patent application, he should be reimbursed for the costs of filing and prosecuting it in the Patent Office, if the agency head determines that the U.S. Government shall take greater than a nonexclusive license. Inasmuch as the contractors are not paid for filing patent applications, it would seem fair that if they expend their own funds they should be reasonably compensated in the event that such patent rights are then retaken by the Government after the Government has, initially, permitted the contractor to take the principal rights. This would be in line with the constitutional requirement that property should not be taken without due compensation.

Also, I believe that section 8(b) should be amended so that the agency head cannot grant any license without the payment of royalties. The major contention of the individuals supporting the Government's taking title of inventions is that the contractors have been given title to property belonging to the public, in other words, it is a giveaway program. It seems to me that if we permit a license to be granted on a royalty-free basis that this, again, is just another type of giveaway program. If the Government is going to become the owner of a patent, it should act as an owner. Patent owners do not give royalty-free licenses unless they are given something in return.

As an adjunct to this, I propose that section 8.(a) be amended to require the Government and/or the agency head to institute appropriate judicial proceedings to enforce the principal ownership rights of the United States in order to prevent others from using its patents without payment of appropriate royalties. This

should be made mandatory to prevent a giveaway program from ensuing. Unless this provision is inserted, no one will take a royalty-paying license with respect to Government patent rights. Without a policeman to enforce a patent, there is no justification for one paying the Government for the privilege of using it. It should be the duty of the Government, as the owner, to see that fair and just royalties are paid so that users of the patent are treated on the same basis.

In conclusion, if the U.S. Government desires to become the owner of patent rights, it should be required to function as an owner and, in essence, that requires it to file patent applications and to collect royalties from others using its patent rights. Further, it should actively enforce its patent rights so that no one free-loads on the Government and on other licensees who have risked their capital in exploiting the invention. Without these provisions, the Government system of title will be nothing more than an empty pit into which everything enters and nothing comes out.

It is hoped that you will give these comments consideration during the hearings to be held with regard to Government patent policy.

Thank you for your attention.

Very truly yours,

DONALD BROWN.

THE UNIVERSITY OF MICHIGAN,
COLLEGE OF PHARMACY,
Ann Arbor, August 26, 1965.

Re S. 1809.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
Senate Judiciary Committee, Washington, D.C.

DEAR SENATOR MCCLELLAN: After writing to you the enclosed letter of August 24, I learned of your understanding attitude during hearings last week. Throughout the hearings, I have been particularly impressed with your desire to get the essential facts relating to the development of compounds made under Government sponsorship.

The statements of Dr. James A. Shannon particularly struck at the heart of the problem, and Mr. Walter A. Munns offered a reasonable solution to the problem. However, I wish to add that the principles suggested by Mr. Munn should be worded in such a way that industry will know in advance of testing and development exactly what its rights will be. Otherwise, no agreements will be reached.

Since the spring of 1962, thousands of compounds have remained on the shelves for lack of proper biological testing. Until a law is enacted, the arbitrary restrictions still in effect will continue to serve as a roadblock.

In the spirit of the final hearings, why can not Dr. Shannon's and other health offices of the Government be directed by the White House to disregard present patent restrictions and to use its discretion in the matter of disposition of patentable inventions until legislation has been passed? Otherwise, time, money, scientific advances, new drugs and lives are needlessly being lost because of a fear that the pharmaceutical industry will take advantage of the public.

I am pleased also that the hearing record will remain open until August 31 to permit inclusion of additional statements. I hope the enclosed materials will be included.

Respectfully yours,

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry
(*Past Chairman, Division of Medicinal Chemistry, American Chemical Society*).

Enclosures.

THE UNIVERSITY OF MICHIGAN,
COLLEGE OF PHARMACY,
Ann Arbor, August 24, 1965.

Re S. 1809.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Judiciary Committee, Washington, D.C.

DEAR SENATOR MCCLELLAN: Please let me introduce myself. I am professsor of pharmaceutical chemistry, the University of Michigan, Ann Arbor, Mich. I was born in Columbia, S.C., in 1912, the son of Edward Burckhalter, of Aiken County, S.C., and of Elizabeth Strain, of Fort Smith, Ark. I have spent 5 years in the pharmaceutical industry and 18 years in university teaching. During the past 9 years, I have been a consultant to the National Institutes of Health. Last year I was chairman of the Division of Medicinal Chemistry of the American Chemical Society. In 1962, I became the first recipient of the Research Achievement Award in Medicinal Chemistry, a $1,000 prize sponsored by the American Pharmaceutical Association Foundation. I have directed the research and studies of 28 Ph. D. recipients and 24 post doctoral associates. I am the inventor of drugs for malaria and amebiasis, and important fluorescent antibody labeling agents used for the rapid diagnosis of infectious disease.

Please excuse the rather immodest statement; I wish you to know how deeply I am involved with research in new drugs and, therefore, with Senate bill S. 1809.

Present patent regulations of the Public Health Service have prevented my students and me from having proper biological testing of the products produced under governmental support. It is ironical that the people through its Congress and President specify that research leading to new drugs be carried out, yet regulations instituted over 3 years ago have stymied those efforts and frustrated those of us who are caught in the middle. Thus, the taxpayers' money is being poured down a rathole, in effect. Bright, energetic students especially wonder what is wrong when our Government works at such cross-purposes.

It has been estimated that research representing less than 1 percent of the funds appropriated by Congress for NIH-sponsored research has any chance of leading to new drugs. To realize the great difficulty of finding new drugs, the total research effort of the pharmaceutical industry at a cost of nearly $300 million per year has produced only one or two truly novel drugs each year. Thus, the possibility of finding a new drug is slight under the most favorable circumstances. Present governmental patent regulations and those suggested by Senate bills which would make an exception of health-supported research will greatly reduce, if not prevent entirely, the likelihood of new medicines from Government support.

To go to the other extreme of no control, would it not be better to have the relatively small outlay of money by Government go freely to the universities, if it means assuring development of novel drugs and reestablishing important collaboration between universities and industry?

The Government entrusts universities to choose qualified faculty and research associates to carry out research. It should rely equally upon the universities in regard to the development of patentable inventions. The only controls by Government should be those requiring reports of patent applications and of development of the inventions to make certain that new substances receive proper biological evaluation. In case of improper development, march-in rights could be exerted, which would be in the interest of the researchers, the university, and the public. Also, present or future antitrust laws, rather than legislation restricting instead of encouraging development of new drugs, seem to me to be the proper course for any abuses by industry.

I am deeply disturbed by the inhibitory effect of present patent regulations and by proposed bills which make an exception of health research. I presume to suggest and hope that S. 1809 will make the following provisions relating to Government-supported research.

1. Patent regulations relating to research in the health sciences will follow essentially the same principles as those in other fields.

2. Disposal of patentable inventions should rest primarily with the grantee and his institution, especially when the patent policy of the institution advances public purposes.

3. The Government should retain royalty-free rights to the inventions for its uses in Government hospitals and facilities.

4. The Government should make certain that patentable inventions are being developed by means of progress reports from the grantee and the collaborating company. March-in clauses should be brought into effect in case of improper development.

5. Present and future antitrust laws should protect the public from excessive costs.

6. Industry should be assured of its rights in advance of biological testing.

7. Proposed legislation should make clear in any patent regulations that marketing rights to industry will not be endangered when industry has borne the cost of research. Those rights should not be lost because a piece of equipment or building purchased by Federal funds was used.

I am enclosing herewith my earlier statements concerning the problem. You will favor me greatly by discussing my letter and the statements with members of your committee.

Sincerely yours,

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry, (Past President, Division of Medicinal Chemistry, American Chemical Society).

Enclosures dated June 8, 1962; March 6, 1963; December 23, 1964; and February 22, 1965.

AN OPINION RELATING TO USPHS PATENT POLICY

JUNE 8, 1962.

Now that the patent policy has been spelled out more clearly by the new patent agreement, and blanket patent agreements are apparently not being processed between universities and the office of the Surgeon General, the overall policy is decidedly discouraging to the testing by industry of products made either wholly or in part under NIH auspices. Even before the new regulation was put into effect, industry was wary of testing a professor's compounds. Now there can be no doubt about industry's attitude.

The only reasons why industry would sign the new agreements are—

(1) as a gesture to a professor in order to allow him to receive research funds, but serious testing would probably not be undertaken,

(2) as a means of finding leads which they could independently pursue—in other words, an evasion of the spirit of the unrealistic regulations.

Since serious testing and evaluation of NIH supported products by industry will cease under present policy, the university chemist must look elsewhere for help. There are three alternatives: (1) private laboratories which test for a fee, (2) university laboratories, and (3) Government laboratories. In either case, an expansion of present facilities would be necessary. For the following reasons, I do not believe the expansion of either would be wise:

First, is the fact that industry is already set up to do rapid, efficient screening. Industry's life depends upon this fact. Because of an understandable lack of incentive to produce new drugs, it is unlikely that either of the two alternative laboratories suggested would ever equal industry's potential.

Testing is an extremely expensive operation. The cost of isolation or synthesis of a new substance is often minor when compared to its biological evaluation. The fees of a private laboratory would thus be prohibitive to the NIH grantee.

I have already had experience with testing in several university pharmacology laboratories. In most cases, results simply are not forthcoming—even after several years. The same is true of governmental laboratories with the exception of the crash program of CCNSC. I should be glad to document these cases in confidence.

There remains the broader question of whether or not it is good for our universities and the National Institutes of Health to take on the business of screening. I am opposed to it. Applied, developmental work should not be the province of the National Institutes and the universities. If it were, the next step would be the manufacture of drugs by Government and universities. Do we want to industrialize Government and university laboratories?

The wishes and objectives of Congress who appropriate NIH funds and the people who pay taxes should be considered. First, I believe Congress and the people are primarily concerned with providing effective medication at reasonable cost. Second, I believe that Congress and the people do not want Government or the universities to perform functions which are most efficiently done by industry. Even prior to the new patent agreement form, industry was wary of expending funds for testing potential drugs whose manufacture they could not control. Thus, for years the full mandate of Congress and the people who have

appropriated increasingly large sums for public health research has not been carried out. It is as if a bridge were built except for one section across a wide river. Such a bridge, despite the cost, is worthless. Does Congress want such a bridge? The missing section, in the case at hand, is proper evaluation of compounds made under Government sponsorship. The new patent form makes the problem all the more acute.

Government, as a nonprofit institution, is rightly a paternalistic one. Thus, what does it matter if industry is occasionally subsidized to the limited extent of the cost of initial preparation of a chemical so long as a valuable new medicament is provided? Actually, industry's research costs are increasing, while truly novel drugs are decreasing in number. A small assist to industry in this case is perhaps even more realistic than a subsidy to agriculture.

Actually, the portion of PHS expenditures designed to lead directly to new drugs is relatively small. Thus, dollarwise a cancellation of the patent policy would constitute a relatively minor gift to universities and industry.

There is a moral question concerning the acquisition of patents by the Government when the inventor or coinventor is an employee of a university or institute whose pay comes entirely or largely from the university or institute. In many cases, the research problem was conceived before application for a grant or contract was made, or the inventive idea comes in the case of a university from a professor whose pay comes entirely or largely from his university.

The Government does not purchase an inventor's brains and background when it pays for work done by a student technician or assistant. The great contribution made by Government in medicinal chemistry is in granting money which pays for new basic chemistry and for the education of a student while he makes promising new compounds usually at the suggestion of his professor. Suppose a professor conceives of a superior method for the production of a drug. He happens to assign the problem to a Public Health research assistant (he might just as well have been a Monsanto fellow). Under present and proposed practice, the university could not control the invention. Years of experience, hard work, and study have enabled the professor to plan research. The Government, of course, did not pay for his education and does not pay his salary. I believe, therefore, that the university and the professor should have much voice in the disposal of such inventions.[1]

Here are my opinions regarding proper patent policy involving Government grants and contracts.

I feel a university, industry, or other institution should be allowed to make decisions regarding patentable inventions developed under grants and contracts. Institutions should be encouraged by the Surgeon General's Office to sign letter agreements relating to disposition of patents. The grantee institution should be allowed to offer nonexclusive licenses to industry. In case a particular company developed the invention, it should have a 5-year exclusive marketing of any products.

It is assumed that a grant or contract is let by the Government, because important research or development is not being carried out. The Government cannot allow an area of research important to the safety or health of its people to be neglected. The Government is a nonprofit, paternal organization. Its policies should favor organizations which are astute enough to employ scientists and engineers who can solve important problems. A university or institute should agree to a policy of nonexclusive licensing, except when a particular company did the developmental work. Then, that firm should be granted exclusive marketing of any product developed for at least 5 years.

J. H. BURCKHALTER,
Professor, Pharmaceutical Chemistry, the University of Michigan, Ann Arbor, Mich.

MARCH 6, 1963.

MR. HERSCHEL F. CLESNER,
Inventions Coordinator, U.S. Public Health Service, Washington, D.C.

DEAR MR. CLESNER: First, let me say that your visit to Ann Arbor afforded me much satisfaction. Your receptive and objective attitude toward the problems arising from the present patent agreement form was most encouraging. In accord with your suggestion, I am outlining some of the specific reasons why I hope the provisions can be altered.

[1] To my knowledge, only Senator Long of Louisiana, Congressman Vivian of Michigan, and Chairman of the Board Boyer of Smith, Kline & French have indicated that the inventor should receive certain rights or rewards. Indeed, creative minds in universities, industry, and Government should receive special reward.

The reasons center around the fact, under present regulations, of industry's unwillingness to engage in the serious testing of compounds developed under PHS auspices, and the NIH grantee's need for pharmacological testing by industry. Based upon my experience and familiarity with industry, testing laboratories, universities, and Government, I believe that the facilities of industry rather than those of the other organizations will bring most rapidly, most efficiently, most economically, and most safely—which is to say to the greatest interest of the public—medicinal agents which are conceived in the universities. Industry's existence depends upon the efficient conduct of screening and it also has the facilities in a single coordinated organization to see that a drug goes over the long series of hurdles. Without patent provisions which will enable industry to participate in the development of a drug, I cannot visualize how an NIH-sponsored drug will reach the people. I shall illustrate the difficulty encountered in our laboratory, under present regulations, of getting over the first hurdle after synthesis—that hurdle being pharmacological testing.

Case 1.—In 1957, we culminated 12 years' effort in the laboratory by the synthesis of a particular compound to be screened in a disease which afflicts about 1 billion persons in the world. Two eminent authorities in the field suggested that only a particular Government laboratory could do the screening, and they expressed great interest in the results. On March 29, 1957, I wrote to the Government laboratory. I have written a total of seven letters and held private conversations with that laboratory in an attempt to obtain the test which is available, but I have failed to secure the evaluation that the two authorities agree should be carried out. The sample is still being held by the Government tester.

Case 2.—On June 26, 1962, we submitted a compound for pharmacological study by a Government facility whose head has expressed in print and orally to me that there is great need for such agents as we have been preparing. Three additional compounds were submitted, the last on November 19, 1962. Acknowledgment of receipt has been made of only the first, and no pharmacological results have been sent to us. I know that screening is currently being carried out, because I visited the laboratory.

Case 3.—A letter and two long distance telephone calls at the expense of my university were made in attempting to reach the head of a Government laboratory which is concerned with a disease that afflicts over 200 million persons in the world. I wished to relay information and to seek to interest that laboratory in the biological evaluation of a nontoxic substance which has shown great promise in animals. No response has yet been received from the director although the initial contact was made on January 11.

Case 4.—Several compounds were submitted about 2 years ago to a professor in a department of pharmacology of a large university. The substances, of potential in cardiovascular disease, were submitted upon the request of the professor. Despite our inquiries concerning results of testing, no response has been received.

Case 5.—Four compounds were recently synthesized in our laboratory under NIH sponsorship; they are identified as GS–82 x 8, GS–82 x 9, GS–82 x 15 and GS–82 x 18. More compounds should follow soon. The substances offer promise in cardiovascular disease. Several of the intermediates are potential anticonvulsants. I do not know where to turn for prompt, reliable testing.

Case 6.—Student ER has recently found how to synthesize types of compounds which offer promise in cardiovascular disease. He, as well as student GS, are concerned about where we can obtain pharmacological testing of their compounds.

Case 7.—Eight compounds, identified as RR–33, 37, 38, 39 and 42; DB–54 x 21 and 24; and IS–71 x 86, are desired by company X as potential drugs. However, their director of research is concerned about their right to market one of them should it show promise. This is a factual situation, even though none of the compounds was synthesized under NIH auspices. The company is concerned lest it might later be shown that some NIH money was expended indirectly during the synthesis. We still hold the compounds, and cannot publish manuscripts until biological data are available.

I realize that in this letter to you it is unnecessary to use arguements growing out of the citing of individual examples of our problems. I am sure from our recent long discussions that we agree on the difficulties. Nevertheless, I shall now take the liberty of generalizing in order to draw a more complete picture in case my letter is examined by a third party who may be less familiar with the implications.

I feel that the first four cases demonstrate clearly the lack of followthrough which is likely to be evident in institutions where basic research rather than biological screening is the principal goal. Also, I refer back to paragraph 2 of this letter in reference to the efficiency of industry in screening.

The answer to the problem, in my opinion, does not lie in the establishment of screening laboratories in Government and university laboratories. Applied, developmental work should not become a principal objective of the National Institutes of Health and the universities. Nor do I feel that the answer lies in having particular tests carried out under contract with private screening laboratories. In the first place, this plan entails a large expenditure of funds which the grantee or the NIH (i.e., the taxpayer) can ill afford to pay. Secondly, such testing does not provide for prompt, coordinated followthrough at each of the succeeding hurdles which lie ahead in drug development. Only industry has the necessary machinery, but present regulations prohibit serious testing and development by industry which contends that it cannot afford to test compounds they cannot market.

While every investigator would like to see his products in use by the public, actually a more acute problem results directly from the lack of prompt, reliable, and extensive pharmacological screening such as only industry can provide. It concerns prompt publication of results. Manuscripts which describe biologically interesting compounds are considered to be incomplete when at least a summary of pharmacological results is not included in the manuscript. Cases 1, 4, and 7, cited in this letter, describe a situation which has prevented the publication of three or four manuscripts from our laboratory. I shall be glad to furnish confirmation of this fact. (Admittedly, case 1 involves a test which only the Government can at present carry out, but it does illustrate the broad problem of inability to publish because of a lack of biological data.) Case 2 demonstrates the inability of a student to include pharmacological data in his thesis and, later, in a journal manuscript. More important, his training in medicinal chemistry has been greatly curtailed because chemical-biological correlations are impossible. Cases 5 and 6 illustrate the dilemma of my students in regard to current studies. Not only do we need tests for future publication but for guidance in future syntheses. Thus, prompt testing can indicate the direct or future synthesis. We are very reluctant to ask NIH for a supplemental grant in order to obtain contractual testing for reasons already given.

A final consideration is that industry is already equipped to test compounds for the main objective of the grant. Also, industry conducts valuable screening of the same compounds in other biological areas, sometimes as many as 10 to 20 additional tests. A single test has been estimated as costing as much as $1,000, but the costs the grantee and NIH nothing.

Again, let me express the pleasure and satisfaction of spending so much time with you in Ann Arbor in the informal discussion of our problems. Your objective attitude is greatly appreciated.

Best wishes.

Sincerely yours,

J. H. BURCKHALTER,
Professor, Pharmaceutical Chemistry.

DECEMBER 23, 1964.

STATEMENT TO DR. GLENN ULLYOT OF SMITH, KLINE & FRENCH

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of present governmental patent policy defeats the purpose of a grant by preventing the evaluation and development of compounds as new drugs. The obvious, predictable effect of the patent regulations thus constitutes a serious deterrent to essential collaboration between universities, industry, and the Government and, therefore, a blow to the future health of the Nation. Scientists from Britain, France, Germany, Japan, and Egypt have stood in amazement when they learned of our present patent provisions.

Aside from the necessity of such collaboration in public health, the regulations ought to be examined in the light of simple legal and moral codes. A researcher

holds the fundamental right to decide how his ideas will be developed. The Government violates elemental individual human rights and dignity if it confiscates a professor's knowledge and experience in exchange for financial support for research assistants, supplies and equipment. Such is the case because of the patent regulations. For the sake of freedom of the scientist and the health of the citizen, the regulations should be changed.

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry, (Past President, Division of Medicinal Chemistry, American Chemical Society).

FEBRUARY 22, 1965.

THE NEED TO CHANGE PATENT POLICY RELATING TO MEDICAL RESEARCH SPONSORED BY GOVERNMENT

Present patent policy controlling potential new medicines initiated or developed under the auspices of the Federal Government assigns all rights to the Government. Three different bills introduced before Congress a year ago and, presumably, to be reintroduced this year, as presently worded, would enact into law the present practice regarding inventions relating to public health.

The bills are the following: S. 1290 (April 9, 1963), Senator McClellan; S. 1433 (May 1, 1963), Senator Long; and S. 1623 (May 28, 1963), Senator Saltonstall.

Based upon my experience in industry and universities and as a consultant to National Institutes of Health, I contended that the present patent practice and that which is proposed by the three bills, while well meaning, fails to recognize the past fruitful collaboration between industry and universities which has produced approximately half of the drugs being used in the world today. The policies are unsatisfactory to virtually all the pharmaceutical companies and to those scientists in universities whose research is most likely to lead to patentable drugs.

I wish first to suggest amendments to the bills which would promote instead of destroy collaboration between the scientists of industry and universities and, therefore, provide better protection to the health and economy of the Nation. Afterward, arguments will be presented in support of the contention that present regulations and the proposed laws are potentially harmful rather than helpful to the cause of public health and welfare.

SUGGESTED AMENDMENTS

1. The form of the present agreement, which industry will not sign, should be amended so that patent rights to industry's own inventions cannot be jeopardized by testing compounds for university scientists performing Government-sponsored research.

2. The principle that industry has rights as a result of collaboration should be recognized by an agreement in advance of testing and development and not afterward. The collaborating firm should receive a period of marketing exclusivity. Five years is suggested.

3. The Government should allow a university to hold patent and property rights while granting the Government royalty-free rights. The university should have a sound patent policy in keeping with he public welfare, allowing other firms to market a drug at the end of the period of exclusivity.

STATEMENTS IN SUPPORT OF PROPOSED AMENDMENTS

The most immediate difficulty caused by the present Public Health Service patent policy is that grantees cannot obtain adequate biological testing of products of their research. Industry which has superior facilities and personnel for screening cannot afford to expend funds without advance assurance of marketing privileges, at least for a limited period of time.

The logical result of a lack of testing or the inadequate testing of potential drugs is that they will not be made available to the sick.

A second difficulty facing the university grantee is the continued and harrowing experience of keeping records in making certain that equipment and supplies

purchased under a Government grant are not used by an industrially sponsored student. (Industry has shown no particular concern over the reversed situation. Ironically, most industrial fellowships in constrast to governmental ones involve no patent agreement; the primary purpose is the support of students in science.) Indeed one of my most time-consuming and harassing duties is keeping separate ideas, students, supplies, and funds based upon sponsorship. The natural demands upon a research professor are so great that he should not be subject to such needless harassment.

Defenders of the present regulations challenge those of us who would change them to offer statistical data in support of our claims. In reply, I use a famous quotation: "There are three kinds of liars: liars, damn liars, and statistics."

How can one obtain statistical facts concerning such a problem as we are facing? Suppose there were a governmental edict requiring that thenceforth all children be taken from their parents at birth and placed in homes for children where they would uniformly receive the best possible education and discipline. After all, it is well known that many children do not receive such advantages at home. How could one provide meaningful statistical evidence against such an edict?

The present patent regulations were made in an arbitrary way. If statistical information was employed in revision of the patent regulations, it pertained to only a portion of the present problem. Present as well as past patent policies of the U.S. Public Health Service failed to consider the necessity for collaboration between scientists in universities and industry. Commonsense tells us that regulations which restrict communication between medical scientists are potentially bad for the progress of science, the economy, and the health of the Nation.

An article in Science (July 24, 1964) describes the importance of collaboration between the two groups of scientists. The fact that foreign nonindustrial researchers outproduced their American counterparts by more than 2 to 1 can be attributed at least partly if not entirely to the fact that the governmental support in America has been very great and, for many years, has been largely self-defeating owing to the requirement of assignment of patents to the Surgeon General. Thus, a large potential of productivity has been ironically dissipated by Government. Scientists from other countries stand in disbelief when they learn of our restrictions.

As a member of an ad hoc committee on patent matters of the Medicinal Chemistry Study Section of NIH, I have suggested that our committee try to obtain certain facts which might be meaningful. But I cannot be too hopeful because the question is one involving principles of economics and philosophy of Government rather than statistics.

Supporters of present patent regulations describe alternate plans as a giveaway of public funds to industry. Actually, the regulations are worse than a giveaway to industry.

Commonsense tells us that policy which assigns patent rights to the Federal Government will have the general effect of preventing development of potentially valuable drugs. Industry has made its position statistically clear at least in this regard. Based upon basic principles of economy, their vote has been almost unanimously opposed to testing Government-sponsored products. Under our system of free enterprise, industry cannot afford to pour time and money into developments which it cannot control for at least a reasonable period.

Commonsense tells us that policy which assigns patent rights to the Government will tend to discourage the application for patents. Commonsense also tells us that a policy which either assigns patent rights to the Government or tends to discourage patents is a policy which gives away not only governmental funds but the talents of university scientists to socialistic and communistic countries which own their industries and, therefore, need not obey the rules of private enterprise. Admittedly, these same countries already confiscate industry's patented inventions, but the policy of the Federal Government should not be the ironic one of making further contributions to socialistic countries while simultaneously depriving its industry of the right to develop promising new agents.

In other words, either patent assignment to Government or the failure to patent, can reasonably be said to have the effect of encouraging socialism and communism abroad at the expense of American industry. The policy would also tend to encourage socialism at home, for, if Government continues to expand its support of research under present patent policy, industry will become increasingly a contractor for Government and essentially will be owned by Govern-

ment. Such social changes probably were not the intent of Abraham Lincoln when he said that patents add the fuel of interest to the fire of genius.

The question might arise as to why a professor continues to supervise and conduct research under Government auspices when he cannot cooperate with industry in necessary development. An answer is provided in the fact that Government grants support students. Faculty cannot easily refuse such support once it has been established. Professors and students are interested in mechanisms of drug action and in contributing to knowledge in that area. They cannot and do not wish to change these interests, which are directed toward the welfare of mankind. They seek and need the competent assistance of industry for confirmation of their theories and development of their products.

The question arises as to why certain pharmaceutical organizations seek to bring about a change in PHS patent regulations. They are suspected of being motivated by the prospect of profit at Government's expense. This suspicion is indeed well founded. Industry must make a profit to survive. But scientists in industry are also motivated by the wish to resume fruitful collaboration with their academic colleagues and by their desire to help faculty and students test their theories. Nevertheless, virtually all pharmaceutical companies refuse to test PHS-sponsored preparations since they presently have no advance assurance that their investment will be protected and since they cannot risk losing large investments in their own related research. Industry regrets to see the inefficient expenditure of public funds which results from present policy. Herein lies its main concern. Industry does not need the compounds of universities to survive, but we in the universities need the testing facilities of industry in order to train our students and to fulfill our obligations in Government-supported research.

A proper function of Government is to support education and research in neglected areas when needed for the national welfare. Thus, governmental cooperation with industry enables industry to help the economy and to pay taxes so that Government can support education and research in universities. Present patent regulations relating to public health interrupt that cycle, with industry, universities, and the public as losers. The Nation's antitrust laws are designed to protect the public from abuse by industry in all areas. That patent regulations involving drugs should constitute a special case is a mistake created through misunderstanding, emotionalism, and political opportunism. The same basic laws of economics and motivation control the search for new products, whether they be food, armaments, safety devices, or drugs.

JOSEPH H. BURCKHALTER,
Professor, Pharmaceutical Chemistry,
the University of Michigan, Ann Arbor, Mich.

CALIFORNIA RESEARCH CORP.,
San Francisco, Calif., June 16, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Patents, Trademarks, and Copyrights Subcommittee,
Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The following remarks express my views and those of my company on legislation proposed by S. 1809 that would establish a uniform national policy concerning inventions made through research supported by public funds.

California Research Corp., a subsidiary of Standard Oil Co. of California, is an organization engaged primarily in research and development on products or processes related to petroleum. We have in past years undertaken an appreciable amount of Government-sponsored research: but in relation to our total program, this has been a small fraction of our total effort—not exceeding 3 percent in any 1 year. We are glad to undertake such contracts without profit to us where we have a particular background of knowledge or experience that can be of benefit in a Government program.

In my opinion, S. 1809 is a good bill and will provide a reasonable solution to a complex issue. A comprehensive bill of this type establishing basic guidelines of Government patent policy for inventions resulting from Government research is generally consistent with the late President Kennedy's statement of patent policy of October 1963, with which we were also in agreement. We would be opposed to legislation, whether it be a uniform national patent policy or included in

specific research authorization bills, that are contradictory to the guidelines set forth in President Kennedy's statement.

Many private firms such as ours are willing to utilize their background of knowledge and experience on Government-sponsored research projects without profit. The most rapid progress in such projects is usually made when company scientists assigned to it are able to draw freely on the background knowledge the company has accumulated over many years of experience. The Government agency is thus able to obtain the most for their research dollar.

The incentive for a company to undertake Government-sponsored research will be diminished greatly if the price of contributing its special competence is the the requirement that it must give the Government exclusive title to inventions and technical information developed and made possible by millions of dollars of previous company investment in facilities and background research. In our opinion, Government agencies will find it difficult to obtain contracts for research in many cases if this requires the contractor to place in jeopardy his proprietary position.

I do not intend to imply from the foregoing that the contractor should always acquire title to inventions. There are situations where it is reasonable that the Government should acquire title. It is essential that Government administrators be given flexibility to meet these situations without adopting the title policy throughout. S. 1809 recognizes this and we are in agreement with the principles it sets forth.

Certain aspects where S. 1809 could be clarified have been pointed out by witnesses at the recent hearings before the Senate Judiciary Subcommittee, with many of which we concur. For example, the section on compulsory licensing, section 3(b)(4), would be improved, we believe, if the reference to "reasonable terms and conditions" were amended to include "and at a reasonable royalty." However, it is not my purpose at this time to review these suggestions in detail, rather they should be left to the committee to decide on the basis of the various recommendations made by industry representatives.

I believe that S. 1809 provides a proper balancing of private and public interests. It will meet the Government needs while furnishing a reasonable incentive and protection of proprietary rights to companies able to make a real contribution to Government research programs.

Sincerely,

A. H. BATCHELDER, *President.*

DELIO AND MONTGOMERY,
COUNSELORS AT LAW,
New Haven, Conn., June 16, 1965.

Re Government patent policy and hearings with regard to S. 789, S. 1809, and S. 1899.

Senator JOHN L. MCCLELLAN,
Chairman, Senate Judiciary Subcommittee on Patents, Trademarks and Copyrights, U.S. Senate Office Building, Washington, D.C.
(Attention of Mr. Stephen G. Haaser.)

SIR: In view of the hearings being conducted by your subcommittee and the importance of such proposed legislation touching on Government patent policy, I should like to submit to the subcommittee for inclusion in the hearing records the views of the writer as chairman of the legislative committees of both the Connecticut Bar Association (Patent, Trademark, and Copyright Section), and the Connecticut Patent Law Association.

If any clarification or discussion is deemed necessary or advisable, kindly let me know.

Thank you.

Respectfully submitted.

ANTHONY P. DELIO.

This is the prepared statement of Anthony P. DeLio, for inclusion in the record in connection with the hearings on S. 789, S. 1809, and S. 1899.

Anthony P. DeLio is the chairman of the Legislative Committee of the Patent, Trademark, and Copyright Section of the Connecticut Bar Association as well as the chairman of the Legislative Committee of the Connecticut Patent Law Association, and submits this statement on behalf of both associations, not to mention various and sundry inventors and corporate patent owners.

Anthony P. DeLio is a former patent adviser of the Office of Naval Research, U.S. Navy Department, and now the senior partner in the firm of DeLio & Montgomery, New Haven, Conn.

The Federal Government's patent policy will have far-reaching effects upon the economy of this country in the years to come and therefore any legislation touching on this area should be carefully construed and considered. Accordingly, the Congress must address itself to the question of the Government's patent policy with well reasoned criticism and understanding.

As one begins an investigation into this area, two policies are evident. One policy is the so-called title policy, wherein the Government takes title to all inventions developed with or as a result of the expenditure of Government funds, while the other policy is the so-called license policy, wherein the Government takes a license under the particular invention, patent, or patent application, leaving title in the contractor.

BACKGROUND

One of the largest Government complexes involved in research and development is the Department of Defense. In the past it followed a license policy with the Government taking title only in those cases where the national security was a factor. Even when the Department of Defense did not take title there was sufficient machinery available to delay the grant of a patent to a contractor so as to ostensibly "kill" the patent or delay its grant to a point where, once granted, it had no useful life.

Perhaps starting with the Atomic Energy Act of 1954, there was a change in thinking in connection with Government-sponsored research and development programs. By certain provisions in this act; viz, sections 151, 152, and 153, the Government would retain title or be vested with title to all inventions useful in the utlization of special nuclear material or atomic energy in an atomic weapon. The Space Act of 1958 contained provisions similar to the Atomic Energy Act; viz, sections 305 and 306, whereby the Government could take title to inventions developed with Government funds. The Space Act did contain some measure of flexibility as to the vesting and taking of title, at least as interpreted and administered by the Space Agency to date.

Due to the legislative programs of the late Senator Kefauver and Senator Long, as regards Government patent policy, the late President Kennedy issued a White House policy statement in 1963 setting forth some guidelines for the Government's policy as to patents. Essentially, the policy statement specifies that the policy is established for all governmental agencies with respect to inventions or discoveries "made in the course of or under any contract of any Government agency, but subject to specific statutes (such as the Atomic Energy Act and the National Aeronautical and Space Administration Act), which specifically provide for the disposition of patent rights."

1. Where the principal purpose of the contract is to create, develop, or improve (*a*) products, (*b*) processes, or (*c*) methods which are intended for commercial use by the general public, at home or abroad, or required for such use by governmental regulations;

2. Where a principal purpose of the contract is for the exploration into fields which directly concern the public health or public welfare;

3. (*a*) Where the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, (*b*) where the Government has been the principal developer of the field;

4. Where the services of the contract are (*a*) for the operation of a Government-owned research or production facility, or (*b*) for coordinating and directing the work of others.

Under such circumstances the Government shall normally acquire the principal or exclusive rights throughout the world in and to any invention made.

In exceptional circumstances the contractor may acquire rights greater than a nonexclusive license if the head of the department or agency (with which the contractor is dealing), certifies that the grant of the principal or exclusive rights to the contractor, will best serve the public interest.

The White House policy statement also specifies that greater rights may be acquired by the contractor (that is, greater rights than a nonexclusive license), if, after the invention has been identified, the invention (1) is not a primary object of the contract and (2) the acquisition of such greater rights is necessary to call forth private risk capital.

In another section of the policy statement it is stated that when two or more potential contractors are judged to have presented proposals of equivalent merit, their willingness to grant the Government the principal or exclusive right in the resulting inventions will be an additional factor in the evaluation of the proposals.

The policy statement specifies that where the purpose of the contract is to build upon existing knowledge or technology for use by the Government and the work is in a field of technology in which the contractor has acquired technical competence (know-how, experience, patent position), the contractor shall normally acquire principal or exclusive rights throughout the world with the Government acquiring at least an irrevocable nonexclusive royalty-free license throughout the world for governmental purposes.

If the principal exclusive rights in an invention are retained by the contractor, (1) the contractor must agree to provide written reports at reasonable intervals upon request by the Government agency on the commercial use that is being made or which is intended to be made of the inventions and (2) the contractor and his licensee or his assignee must take effective steps within 3 years after a patent has issued on the invention, to bring the invention to a point of practical application or in the alternative make the invention available for licensing royalty free to competitors.

Notwithstanding the above, where the principal or exclusive rights are acquired by the contractor, the Government shall have the right to require the contractor to license another on a nonexclusive royalty-free basis.

The Federal Council for Science and Technology, in consultation with the Department of Justice, has been commissioned under this White House policy statement to report annually on the effectiveness of the policy and a Patent Advisory Panel has been established under the Federal Council for Science and Technology to work out the details.

In the 88th and 89th Congresses, Senator Long was successful in attaching riders to several bills; viz., the Appalachia bill and others, which riders set forth a title patent policy for the Government.

In recent months the proponents of the title policy have cited various abuses by those dealing in patents; viz., the PKU situation and others, in an effort to gain support for further title policy riders and/or the adoption of an overall title policy as regards Government financed research and development.

THE DIALOG

Historically, the patent system has proven its worth, especially in those nations where the underlying economy is still basically free. Those who accept this view feel that the adoption of a title policy will weaken the patent system with its attendant ill effects upon the economy and the Nation as a whole. As such, any change in the policy from, say, the flexible Department of Defense (license) policy to a title policy must be carefully weighed and analyzed. In addition, until the proponents of a title policy can guarantee no ill effects upon the economy and, more importantly, upon the investment of risk capital, there should be great reluctance to adopt a so-called title policy.

In view of the foregoing, one basic question that should be considered is whether or not the Government needs title in order to satisfy its needs or requirements. Since the Government is not a manufacturer, since the Government does not make it a policy to license inventions for profit, since the Government has a limited staff of patent specialists and since the Government has little expertise in evaluating inventions from a commercial standpoint, it would seem unnecessary and inadvisable for the Government to take title to inventions developed under Government-financed research and development programs. So long as the Government obtains a license under the invention in question, it and the public interest is adequately protected. The reason is that the contractor cannot sue Government contractors for infringement in view of title 28, section 1498, of the United States Code, which states:

"Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the Court of Claims for the recovery of his reasonable and entire compensation for such use and manufacture. * * *"

Since the Government has a license, the contractor having title to the invention cannot proceed against the Government in connection with the invention in question.

On the other hand, leaving title in the contractor stimulates the investment of risk capital to develop the invention commercially, because the contractor has an exclusive property right in and to the invention. In addition, the contractor is inclined to seek and obtain as much foreign patent protection as is commensurate with the invention's field of use and the contractor's foreign enterprises.

Accordingly, it is appropriate to reflect at this juncture as to whether or not Congress should enact legislation and, more importantly, what type of legislation should be enacted. In addition, might it not be advisable to wait for recommendations from the recently announced Presidential Commission to Study the Patent System, before enacting legislation which will have far-reaching economic effects. It is submitted that the Congress ought to "take a minute" to weigh its responsibility to the Nation in connecton with this matter in order to best serve the public interest.

PROPOSED LEGISLATION

There are several bills pending in the Senate, viz, S. 789. S. 1809 and S. 1899 in connection with Government patent policy, and it is important that these bills be carefully viewed in light of the above.

To begin with, S. 1899 (Senator Long, 89th Cong.) prescribes an inflexible title policy, which takes title where Government funds are expended. Regardless of whether the Government needs title, it must take title under S. 1899. As such, the policy prescribed by this bill is not in keeping with the underlying basis of the Presidential policy statement, nor is it in keeping with the best interests of the public. When title to an invention vests in the Government, when a patent is taken out by the Government, and when the invention and patent become available, royalty free, or otherwise, on a nonexclusive basis to all, little, if any, risk capital will be invested to commercially develop the invention in question. In addition, since the Government is not involved in the business of world trade as an entrepreneur, there is little incentive for it to take out patents in other than this country. As such, there can be a loss of (patent) protection to the United States as an entity, with its attendant loss of licensing revenue, which is a gain for the competition. Accordingly, such a title policy would relegate more and more inventions and patents to the growing graveyard of Government-owned inventions and patents.

As far as S. 789 (Senator Saltonstall, 89th Cong.) and S. 1809 (Senator McClellan, 89th Cong.) are concerned, these bills are ostensibly compromises between the title and license policies, but prescribe in reality no more than a sugar-coated title policy.

Any one familiar with the workings of large corporations or Government agencies is keenly aware that only on rare occasions will the administrator or his aid give up title to an invention, based upon the criteria set forth in these bills. Once the Government has taken title, it will become even more difficult for the contractor to get title back.

In Senator Saltonstall's bill, S. 789, machinery is set up for the contractor to get title back; but in each instance judgments are necessary which would tax the powers of a Solomon. Accordingly, the net result of the Saltonstall bill will be that the Government would invariably take title and in some few instances title might revert to the contractor.

The same applies to Senator McClellan's bill, viz, sections 4 and 5 thereof.

As such, none of the bills currently before the Congress possesses the flexibility of either the Preidential policy statement or the Department of Defense policy.

COMMENTS AND CONCLUSIONS

Under Department of Defense policy, the Government obtains a license under all inventions developed as a result of Government-financed research and development programs. If a policy is adopted which is practically or ostensibly a title policy, it will drive many prospective contractors with the desired and necessary expertise out of the business of Government contracts. In addition, those who continue to seek and obtain Government contracts will be careful to

keep a clear line of demarcation between company-sponsored and Government-sponsored research programs. When research is to be conducted in an area which is sensitive as concerns Government patent policy, the contractor will see to it that no Government funds are used in an effort to avoid any question of the Government's title to an invention or patent. The result is that the Government will not end up with a license—it will end up with nothing. As such, procurement by the Government will be subject to an increasing percentage of propietary rights, which are unencumbered by Government licenses, with the net result that the public interest will not be best served.

In view of the foregoing, it is suggested that a policy must be adopted which is flexible enough to give the Government title in those instances where it is necessary for the Government to have title, but which first resolves the doubt of title in favor of the contractor, reserving to the Government a royalty-free, irrevocable, nonexclusive worldwide license.

In an effort to meet this challenge and to satisfy the requirements for a practical everyday policy concerning Government-sponsored research and development, please find attached hereto a bill which has been approved by the Connecticut Bar Association and the Connecticut Patent Law Association. In many respects the proposed bill is similar in its tone and approach to the bills of Senator Saltonstall and Senator McClellan. It leaves title in the contractor with the Government always obtaining a license and provides machinery and procedures whereby the Government may take title in order to best serve the public interest, viz, the public health, safety, and security.

It is respectfully urged that this subcommittee and the Judiciary Committee of the Senate give careful consideration to the question of Government patent policy and the proposals before them and that each member pause "just a minute" to insure to the public that its interests will be best served by any legislation to be enacted.

Respectfully submitted.

ANTHONY P. DELIO.

S. ——

IN THE SENATE OF THE UNITED STATES

A BILL To prescribe a national policy with respect to the determination and disposition of property rights to inventions made in the course of experimental, developmental, and research work conducted under contracts or arrangements with the United States Government, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Inventions Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) The term "executive department" includes any executive or military department of the United States.

(b) The term "agency" denotes any independent establishment in the executive branch of the Government, the Government Printing Office, the Library of Congress, and any wholly owned Government corporation.

(c) The term "head" used in conjunction with executive department or agency denotes the head of such executive department or agency, except that the Secretary of Defense shall be the head of the Department of Defense and of each military department thereof, and in the case of any authority, commission, or other agency, control over which is exercised by more than one individual, such term means the body exercising such control.

(d) The term "contract" means any contract, agreement, commitment, or understanding entered into between any executive department or agency and any other person for the acquisition of any property or the performance of services by or on behalf of any executive department or agency. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract.

(e) The term "person" includes any individual, corporation, partnership, firm, association, institution, or other legal entity.

(f) The term "invention" means any invention, discovery, or improvement which appears to be reasonably patentable under title 35, United States Code.

PROPERTY RIGHTS

SEC. 3. The Congress hereby declares it to be the policy of the United States that—

(a) Each contract entered into by an executive department or agency of the United States and each subcontract at all tiers thereunder, which has as one of its purposes the performance of experimental, developmental, or research work, shall contain provisions prescribed by such executive department or agency governing the disposition of property rights in and to inventions made in the performance of such work thereunder. Said provisions shall state that the contract is subject to the terms and conditions of this Act. Said provisions shall grant to the United States a proprietary interest greater than that set forth in subsection (b) of this section in any invention first conceived or reduced to practice in the performance of such work where a determination by the pertinent executive department or agency that the public interest requires that the Government receive a proprietary interest greater than that set forth in subsection (b) of this section. The determination of whether the public interest will best be served by Government ownership of an invention developed under a contract shall be based upon such factors as whether the contract—

(1) calls for exploration into fields which directly concern the public health, safety or security and the inventions likely to result therefrom would be useful directly in such fields; or

(2) is intended to produce one or more end items the use of which is likely to be required by law in furtherance of the public health, safety or security.

(b) As to those contracts not within the purview of subsection (a), there shall be reserved to the United States in all instances an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice throughout the world, by or on behalf of the United States or by any foreign government pursuant to any treaty or other agreement with the Government of the United States, or for the Government for governmental purposes, of each such invention which results from performance of such contract.

(c) Acquisition of the rights specified in subsection (b) of this section shall be deemed sufficient in all cases for the protection of the public interest, so that additional rights shall not be required by any executive department or agency except upon certification by the head of such executive department or agency with respect to particular inventions that such additional rights are required under section 6 hereof.

(d) The acquisition of a proprietary interest greater than that set forth in subsection (b) of this section by the Government to an invention shall be subject to the reservation of an irrevocable worldwide, nonexclusive, royalty-free license to the contractor and to its existing and future associated and affiliated companies, if any, which license shall be assignable to the successor of that part of the contractor's business to which such invention pertains.

(e) Subject to the provisions of subsection (b) of this section, an executive department or agency may, whenever a contract provides for the taking of rights to an invention by the United States under subsection (a) of this section, waive the rights of the United States to such invention at any time on such terms and conditions as may be determined to be in the best interests of the United States. Waiver shall be granted under the following criteria:

(1) where the contractor has had substantial experience and background in the field of technology to which the invention pertains and the invention would have been a probable result of acquired skill or experience;

(2) where the invention is a natural adjunct to other inventions, the patents for which are owned by the contractor, and which in the course of time would probably have been developed by the contractor;

(3) where the invention is of such character that its commercialization would depend upon speculative investment to a substantial degree of a kind ordinarily facilitated by patent protection;

(4) where the invention has resulted from the continuation of development work in which the contractor has invested amounts which are substantial in comparison to amounts allocated to such development by the Government under the contract; or

(5) the invention has been developed by a small business concern, within the meaning of section 3 of the Small Business Act, whose economic welfare and competitive position would be enhanced through acquisition of title to the invention.

must be reported immediately to the Surgeon General. When this is done, the investigator receives by return mail an outline for invention report, consisting of 18 questions and included as exhibit 2 in the Grants Manual. I personally have received such a questionnaire. If I were to answer it haphazardly, I could do so in half a day; if I were to answer it in a really proper manner, it would take several days. Only after the investigator has filled out this questionnaire and returned it to the NIH will the legal staff of the NIH decide whether this material is patentable, regardless of whether the investigator wishes to take out a patent or even whether he considers the material patentable.

I maintain that this procedure is not enforceable and would have preposterous consequences if any attempt were made to enforce it. Of the several thousand NIH grants, at least 50 percent are certain to contain some invention or discovery falling within the definition of NIH form PHS 3945. Many of the NIH grants will contain several such inventions or discoveries. Among the grants in chemistry or biochemistry, I would estimate that over 80 percent fall within this category. Any patent lawyer will confirm that the question of "patentability" is very difficult to answer and that the answer depends largely on one's attitude. If one is interested in securing a patent, a patent attorney can make a good case that a given subject is patentable, while the exact reverse can be accomplished if the attorney is trying to prove that a given subject is not patentable. One can estimate conservatively that, of all chemical patents issued yearly by the U.S. Patent Office, 50 to 70 percent would be declared invalid if carried through the courts—the reason being precisely the uncertainty which exists about the definition of a real invention. I wonder whether the Surgeon General is aware of the fact that many patent applications are filed and patents granted in the chemical and pharmaceutical areas that do not include any experimental work at all—all of the work on the invention or discovery being "paperwork" and that such patents are entirely legal under our present system.

With this information as background, I performed the following experiment: I selected at random only one issue of a chemical journal—the April 1963 issue of the Journal of Organic Chemistry—and then picked out all the articles which acknowledged NIH grant support. There were 17 such articles in the April issue. Of these, I could select only three (pp. 900, 1075, and 1086) which I could definitely say did not contain patentable material. In three other instances (pp. 936, 945, and 1128), an excellent case could be made for patentability, including a statement of utility. Of the remaining 11 articles, in 7 (pp. 923, 928, 942, 964, 1098, 1108, and 1119) a good case could be made for patentability and in 4 (pp. 1004, 1015, 1037, and 1041) a weak case.

According to the present NIH rules, 14 of these 17 investigators should have filed an invention record and subsequently answered the 18 questions of the outline for invention reports. Reckoned conservatively in man-hours, this would require 1 to 2 months. But the real work would start only when the NIH legal staff received these documents and started wading through them. I would estimate that this experiment would have to be multiplied at least several hundredfold each year to cover all relevant grants and that the NIH would require a legal staff which would have to be much larger than the examining staff of the U.S. Patent Office. It would also involve several hundred man-years of investigators' time to handle all the reports, answers, etc., and it should be remembered that the most productive investigators are those whith several collaborators, who very likely have many such invention reports each year at various stages of processing.

To complete the above-outlined small experiment from the April 1963 issue of the Journal of Organic Chemistry, I recommend that the Surgeon General put a member of his staff on the job of checking the 17 grants to determine whether any invention statements have been filed. The chances are excellent that he will find none. The chances are poor that he will find 2 or 3 and the probability is infinitesimal that he will find even 10—let alone the experimentally determined 14 which would be required.

Does this mean that all of these investigators are dishonest, that they are using NIH funds without fulfilling regulations, that they are filing patents surreptitiously? The answer is that the present patent policy is impractical and unenforceable because it cannot be practiced—either by the investigators (who would end up having little time for research if they followed literally the patent regulations) or by the NIH (which does not have even a fraction of the legal staff necessary to handle hundreds of such reports annually). I conclude, therefore, that the patent policy should be changed, before an uproar is raised

fied in subsection (b) of section 3 pursuant to the provisions of subsection (a) of section 3, or that he shall take no greater rights than are required by subsection (b) of section 3 because the invention does not come within any of the categories enumerated in subsection (a) of section 3. Such determination shall be based upon that criteria enumerated in section 3 (a) and (e) hereof; and

(2) if the executive department or agency head determines to take on behalf of the United States a proprietary interest greater than that provided in subsection (b) of section 3, he shall transmit to the contractor written notice of his intention, which notice shall—

(A) specify the nature of the proprietary interest in that invention which the executive department or agency head claims on behalf of the United States;

(B) state with particularity the basis for belief that the United States is entitled under this Act to take such interest in that invention; and

(C) accord to the contractor, or his duly authorized representative, an opportunity for a hearing, conducted pursuant to the provisions of subsection (c) of this section upon the question whether the United States is entitled under this Act to take such proprietary interest in that invention.

(b) If no application for a hearing is made by the contractor, or any other interested party, within sixty days after receipt of notice by the contractor, or if the executive department or agency head determines upon the record of any such hearing that the United States is entitled under this Act to take a proprietary interest greater than that provided in subsection (b) of section 3, the executive department or agency head shall issue with respect to that invention a written declaration of taking on behalf of the United States which shall—

(1) identify with particularity the invention to which it relates; and

(2) specify the nature of the proprietary interest therein so taken on behalf of the United States. Such declaration shall be served upon the contractor or upon his duly authorized representative, and a copy thereof shall be transmitted to the Commissioner of Patents. The executive department or agency head shall advise the Commissioner of Patents promptly concerning the pendency and result of any judicial review of such declaration.

(c) Whenever any section of this Act provides for a hearing to be conducted by an executive department or agency into the question of the proprietary of any determination made thereunder, there shall be issued to the parties involved a notice of intention to hold a hearing not less than sixty days after the mailing of such notice. Any hearing held under this subsection shall be conducted in conformity with the provisions of the Administrative Procedure Act. There shall be a right of judicial review under section 7 of this Act to any decision by an executive department or agency under this subsection.

JUDICIAL REVIEW

SEC. 7. Any person aggrieved by any declaration under sections 4, 5, and 6 may, under the Federal Rules of Civil Procedure, title 28, United States Code, obtain a review of such determination in the United States Court of Appeals for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides by filing an application for such review within sixty days after notice of such declaration or determnation. Findings of fact made in the administrative proceeding, if supported by substantial evidence, shall be conclusive. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

RIGHTS BY IMPLICATION

SEC. 8. No rights granted under any invention or patent pursuant to section 3 or section 5 hereof shall be deemed to grant any rights by implication under any other invention or patent.

GOVERNMENT PATENT PROTECTION AND USE

SEC. 9. (a) Whenever proprietary rights specified under subsection (a) of section 3 are taken to an invention by and in behalf of the United States through a declaration of taking, the head of the executive department or agency involved

company as well as by investment of capital in the huge vats and other equipment necessary for the commercial production of a drug by fermentation and, of course, not available at most universities. Later the chemical structure and a chemical method for synthesizing chloramphenicol commercially were discovered at the company. Not only was this the first antibiotic produced by chemical methods rather than by fermentation, but the chemical work enabled the initial costs of preparing this lifesaving drug to be reduced greatly. This is a prime example of beneficial cooperation of university personnel with industry. If Dr. Burkholder had had a Government grant in 1947 and the restrictions of S. 1899 and S. 1809 in their present form were in force this very important therapeutic agent might not have been made available to the public.

Another example of university-industry collaboration can be found in the pioneering drug diphenhydramine ("Benadryl"). The chemical was prepared by an academic group at the University of Cincinnati under Dr. George Rieveschl and was sent to a pharmaceutical company for testing as an antispasmodic. During the general testing of the compound, its very potent antihistaminic activity was discovered. Today this drug is considered to be the "father" of the antihistamines and still one of the most potent and widely used of this class. Once again, a most unusual drug might have been lost without industry-university collaboration.

Literally tens of thousands of diabetics are alive today because of the availability of insulin, first discovered by Frederick Banting at the University of Toronto and made available to the public by collaboration with an American drughouse.

As one final example, one can cite the spectacularly impressive record of the so-called cortical hormones: ACTH isolated by Li at California; cortisone by Kendall at the Mayo Foundation, to mention two. Through industry collaboration not only these but improved drugs based on these early leads are now available for treatment of a host of diseases.

Turning to the present situation, which has arisen largely because of restrictions initiated by the National Institutes of Health, we find that collaboration between NIH grantees and industry has substantially ceased. Under these restrictions all property rights to a chemotherapeutic agent revert to NIH if any NIH funds, however small, are involved. Let us consider a couple of examples of the potential harm arising from such restrictions.

For the past few years with NIH support I have been interested in constituents of certain plants as possible therapeutic agents. Among others we have found a tree bark which contains a substance which, through collaboration with a pharmaceutical firm prior to 1963, we have found exerts a profound effect in lowering blood pressure in animals. So far we have not succeeded in separating the active substance from the other constituents of the bark largely because we have had no way of securing the necessary animal tests since 1963. The company in question, in common with practically all others, does not feel that it can sign the overly restrictive NIH patent agreements which must be executed by the company prior to the collaborative work.

A colleague of mine has on his shelf some 26 compounds synthesized with NIH support and specifically designed for treatment of hypertension and atherosclerosis. He is unable to get these screened by any pharmaceutical firm.

The shoe also fits on the other foot. The same colleague also has on his shelves 11 compounds synthesized for control of malaria (a very pressing problem now in southeast Asia due to development of resistance to the commonly used drugs). Support for the synthesis of these substances came from a pharmaceutical firm which naturally desires to retain rights to them but which has no facility for screening them for antimalarial action. Negotiations with NIH, which does have such facilities, for doing the screening, revealed that should NIH screen them all rights would revert to the Government.

Thus, collaboration in this vitally important area has been effectively blocked with resultant unfortunate effects, to say the least, on the general public health, welfare, and safety.

In the light of the preceding discussion, may I therefore suggest the following modification of the McClellan bill (S. 1809), which otherwise I consider an excellent bill, for your serious consideration in the public interest.

(e) The Saline Water Conversion Act of 1961 (75 Stat. 628) is amended by striking out section 4(b).

(f) The Coal Research and Development Act of 1960 (74 Stat. 336) is amended by striking out section 6.

(g) Section 4 of the Helium Act, as amended by the Helium Act Amendments of 1960 (74 Stat. 918) is amended by striking out the following language: "*Provided, however,* That all research contracted for, sponsored, cosponsored, or authorized under authority of this Act shall be provided for in such a manner that all information, uses, products, processes, patents, and other developments resulting from such research developed by Government expenditure will (with such exceptions and limitations, if any, as the Secretary may find it to be necessary in the interest of national defense) be available to the general public.

(h) The Arms Control and Disarmament Act of 1961 (75 Stat. 631) is amended by striking out section 32.

(i) The Water Resources Research Act of 1964 (78 Stat. 329) is amended by striking out section 303.

(j) The Appalachian Regional Development Act of 1965 (79 Stat. 20) is amended by striking out section 302(d).

EFFECTIVE DATE

SEC. 14. This Act shall take effect on the first day of the fourth month beginning after the date of enactment of this Act.

UNIVERSITY OF DENVER,
DENVER RESEARCH INSTITUTE,
Denver, Colo., June 8, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: I should like to submit for the record a brief statement of my personal views on S. 1809 and S. 1899 concerning Federal patent policy on which your subcommittee held hearings last week.

In summary, I favor, with a few exceptions, the terms of the chairman's bill, S. 1809, and oppose the terms of Senator Long's bill, S. 1899.

For 10 years, my applied economic and management research work has required frequent and intimate contacts with industry. During the last 5 years, the bulk of these contacts have been with technically oriented firms nationwide. The problems of Federal patent policy have entered into many aspects of this research work (which has been sponsored both by Federal and private funds).

This experience, plus study of the extensive hearings and publications on the subject of patent rights arising from federally sponsored contract research, have led me to conclude that with a few exceptions, patent rights should rest with private industry or should be made available on a limited-exclusive basis to private industry. Hence, my views are largely in agreement with S. 1809.

Proponents of the opposite viewpoint make very appealing arguments about the merits of a Government title policy such as advocated in S. 1899. Almost none of these arguments stands the test of scrutiny, in my opinion. For example, the argument is made that the Federal Government should take title to all patents arising out of research supported by the taxpayers to protect the public interest from "giveaways." But, rather than protecting the public interest, I believe a Government title policy harms the public interest by discouraging the commercial application of the fruits of the public's R. & D. tax dollars—thus tending to deny the public new, better, or less expensive products. I have been convinced of the validity of industry's argument in this regard. Since industry usually has to invest 10 or more times the R. & D. cost of an invention in designing, producing, and marketing it, there is a greatly reduced incentive to invest large sums to develop inventions on which the patent rights are nonexclusive.

Returning to the chairman's bill, S. 1809, I feel certain that my few objections to this bill were covered in detail in testimony made to your subcommittee last week. I only wish to state my belief in the generality that the more remote the Federal Government can place itself in such administrative matters as selecting licensees and protecting licenses from infringement, the better. Such activities

The granting of a waiver by an executive department or agency shall be accompanied by findings of fact made by the head of such executive department or agency, which describe fully the basis under which the waiver was granted.

(f) Whenever the provisions of subsection (a) of this section require the head of an executive department or agency to take a proprietary interest in an invention greater than that specified in subsection (b) of this section, he shall take such greater interest unless he determines, after examination of the facts of the particular case, that special circumstances indicate that the contractor should receive all right, title, and interest in and to the invention, subject to the proprietary interest reserved to the United States in subsection (b) of this section, and that the public health, safety or security would not be affected adversely as a result of the contractor receiving said right, title and interest. The criteria for making this determination shall be—

(1) that the interest of the particular executive department or agency will not be adversely affected;

(2) that the interests of other executive departments or agencies of the Government will not be adversely affected;

(3) that there is a present commercial value and potential public use for the invention; and

(4) that the developer of the invention can reasonably satisfy public demand for and use of the invention.

Prior to making this determination, the head of the executive department or agency shall make findings of fact thereof. These findings of fact shall be communicated to the heads of other executive departments or agencies whose interests may be affected by the determination. The responses of such other executive departments or agencies shall be considered by the head of the executive department or agency concerned when its determination is made.

FURNISHING OF INFORMATION

SEC. 4. (a) Any party entering into a contract under section 3 hereof shall furnish to the appropriate executive department or agency a written report which shall detail full and complete technical information concerning any invention, discovery, or improvement made in performance of such contract, in accordance with such rules and regulations as the executive department or agency may prescribe.

(b) Any patent which issues to a contractor on an invention developed in the performance of a contract shall become the property of the United States and the patent be dedicated to the public, if upon a finding made pursuant to subsection (c) of section 6, and in the event an appeal therefrom is taken, such finding is affirmed by a proceeding brought under section 7 hereof, that the contractor knowingly and willfully withheld reporting of the invention required by an applicable contract.

LICENSING OF PATENTS

SEC. 5. Whenever the Government takes a proprietary interest in an invention greater than that specified in subsection (b) of section 3 and makes available to the public use thereof, the Government shall grant to the contractor which produced the invention an irrevocable exclusive, royalty-free license for practice of said invention if within three years of the taking of such interest by the Government, no actual use is made of said invention by another party. Such license shall be granted upon application by the contractor to the pertinent executive department or agency.

ADMINISTRATIVE PROCEDURE FOR DETERMINATIONS

SEC. 6. (a) Whenever the head of an executive department or agency shall determine that an invention, made in the performance of an obligation arising from a contract where the United States has taken rights no greater than those specified in subsection (b) of section 3, has given rise to new, unusual, and compelling factors related directly to the public health, safety, or security which did not exist at the time the contract was negotiated, but which require reconsideration of the rights established under said contract, he shall within sixty days after receipt of the information on which that belief is based—

(1) make a determination supported by findings of fact that he shall take on behalf of the United States a proprietary interest greater than that speci-

able for such purposes and I know of no Government agency whose mandate it is to get drugs through FDA approval. If there are any instances where a Government agency has in fact accomplished this, such an occasion must be so rare as to represent the exception that proves the rule that in this country virtually all of the drugs presently employed were brought to the patient and the physician through a pharmaceutical company.

Suppose some of the basic research leading to a potentially useful drug is accomplished in a university under partial or even complete NIH subsidy. The distance between that discovery and the ultimate approval of the drug by the FDA must be measured in years and in hundreds of thousands or in millions of dollars. Would a pharmaceutical company ever take that financial risk without having some assurance of protection for at least a certain period of time?

My own feeling is that, under such conditions, such a company should be given a semiexclusive license (the other partner obviously being the Government, which should retain rights to such an invention) for at least 5–8 years, starting from the date that FDA approval had been granted. There is a very good reason for that proviso. If, for instance, the invention dealt with a machine, a company could estimate the potential market, the size of its own investment required to bring the product to the market, and the chances of recovering its investment and of ultimately making a profit. This is clearly not the case with a drug. Some of the most promising drugs fell by the wayside after several years of extensive clinical testing. Furthermore, the less there is known about a given clinical use and the less precedence there is for similar drugs in that area, the longer it takes the FDA to grant approval—and properly so. I myself have been the discoverer or codiscoverer of a number of important drugs which are now used clinically. In two instances—the first antihistamine and one of the first oral contraceptives—no similar drug existed anywhere on the market and a great deal of extra work had to be done to convince the FDA of the safety and efficacy of such drugs. In the case of the oral contraceptive, the time interval between my initial chemical discovery (while working at Syntex) and the FDA approval was 10 years, 6 of which were spent solely on clinical work. There simply must be some protection to the company for the risk it assumes. If there will be no protection, then, in my opinion, the net result of section 4(a)(2) will be that very few if any potential drug discoveries made in universities under either partial or complete Government support will reach the public.

3. The definitions of "inventions made" in sections 2(e) and (g) are somewhat vague, at least in the area of drug research. According to the present operation of the Patent Office, a discovery is considered patentable only when a utility has been demonstrated. In a drug, such utility is its biological activity or the fact that the substance can be transformed into another one with biological activity. Who is the inventor under the definition in your bill? The person who first made the substance, or the one who discovered its utility? The drug field is replete with examples of the following type:

Frequently a chemist will synthesize a substance in connection with research that may have absolutely nothing to do with public health. The research work may have been completed months or years ago and then one day this substance is submitted to a pharmaceutical company for general pharmacological screening, which uncovers an interesting biological activity. Usually, further chemical modifications must be made (in this instance, probably in the drug firm's laboratory) before the best compound is obtained which can then be put through the laborious toxicological and clinical programs. Even if the very first compound submitted by the outside chemical investigator were the ideal one and required no further chemical modification, the complete biological, toxicological, and clinical work would still be required. Who is the inventor under your present bill? The chemist, who made the substance the first time, at a university under a Government research grant, but had no evidence of utility for it and hence could not patent it even if he wished to do so, or the pharmacologist in the drug firm who discovered the utility? How would such a case be handled?

The second and equally frequent occurrence is where the chemist has a very definite biological goal in mind when he first commences on his synthetic research. When the compound is finally tested, it is found to be inactive or toxic. However, when the same substance is screened for some completely different biological activity, it is found to be active. Again, who is the inventor?

I have described two extreme cases, but there are many others that fall in between. In each instance I have assumed that the pharmacological screening

in the taking of said rights may make application to the Commissioner of Patents for the issuance of a patent therefor to such executive department or agency head on behalf of the United States. If it is determined by the Commissioner of Patents that such invention is patentable, a patent shall issue to such executive department or agency head on behalf of the United States.

(b) Each executive department or agency head may grant a royalty-free, nonexclusive license for the practice of any invention for which a patent is held under this Act on behalf of the United States if such license is granted in furtherance of a purpose set forth in subsection (f) of section 3. If such nonexclusive license fails to result in the practice of an invention, such executive department or agency may thereafter grant an exclusive license subject to section 5 of this Act, provided a finding of fact is made by the head of such executive department or agency that an exclusive license is necessary to insure practice of the invention. Any party aggrieved by such finding of fact may bring proceedings under subsection (c) of section 6 of this Act. Any license under this subsection may be granted for the effective period of the patent or for a more limited period of time.

REPORTS TO THE CONGRESS

SEC. 10. The head of each executive department or agency which awards any contracts of the class described in section 3 shall submit semiannual reports to the Congress which contain—

(1) the number of inventions disclosed pursuant to such contracts;

(2) the number and general nature of such inventions with respect to which the executive department or agency acquired no greater right than those specified in subsection (b) of section 3, and a summary of the findings of fact upon which such determinations were made;

(3) the number and general nature of inventions coming under the categories described in subsection (e) of section 3 with respect to which no rights greater than those specified under subsection (b) of section 3 have been taken, and a summary of the findings of fact upon which such determinations were made; and

(4) the number and general nature of such inventions in which the executive department or agency has acquired a proprietary interest greater than a royalty-free license.

RULES AND REGULATIONS

SEC. 11. The Secretary of Commerce shall promulgate rules and regulations for the administration of this Act. Each executive department and agency of the Government may issue supplemental rules and regulations required for its internal administration and consistent with the rules and regulations promulgated by the Secretary of Commerce.

SEVERABILITY CLAUSE

SEC. 12. If any provision of this Act, or the application of such provision to any person or circumstance, is held invalid, the remainder of this Act or the application of such provisions to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

TECHNICAL AMENDMENTS

SEC. 13. (a) The Atomic Energy Act of 1954 is amended by striking out section 152 thereof (42 U.S.C. 2182).

(b) The National Aeronautics and Space Act of 1958 is amended by striking out sections 305 and 306 thereof (42 U.S.C. 2457, 2458).

(c) The National Science Foundation Act of 1950 is amended by striking out section 12 thereof (42 U.S.C. 1871).

(d) Section 10(a) of the Act of June 29, 1935, as added by section 101 of the Act of August 14, 1946 (60 Stat. 1085), as amended; 7 United States Code 427i(a) is amended by striking out the following language: "Any contracts made pursuant to this authority shall contain requirements making the results of research and investigations available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine."

not be the subject of patent applications or patents benefiting the investigator or the institution. Having stated these two premises, I would now like to point out that the present patent policy is probably unenforceable in its current form and that it can be pernicious if taken literally. Theoretically and legally, this will enable the Surgeon General to terminate most research grants at will if all administrative procedures are not followed by grantees, since he now has this prerogative. I shall demonstrate below with a concrete experiment that the majority of investigators are definitely violating the patent procedure as it is now defined and that they will be forced to continue to do so, because it is completely impractical. I shall also show that, even if the grantees followed the present regulations literally, the NIH would be in no position to handle the problem.

I am presuming that the chief purpose of the NIH grant program is the development of new knowledge and new capabilities in the health sciences and that such information should be made available to the public. The traditional and proper way of making it public is through the medium of scientific publication. I am assuming, further, that it is not the primary or even secondary function of the NIH grant program to secure patents on behalf of the Government. Indeed, in the relatively few cases where patents are taken out by the Government, they are made available on a royalty-free basis, thus fulfilling the concept of availability to the public.

Therefore, the only possible justification for patents is to safeguard the public from private individuals or organizations securing patents on the basis of earlier publications describing NIH-supported work, since such patent applications could be filed within a year of the publication date, provided certain other conditions were met. I imagine that occasionally such a situation may have arisen in the past and it is conceivable that it might arise in the future. However, if we consider the fact that there are well over 10,000 NIH grants in operation per year and that they give rise to probably a larger number of publications, it is false economy in the extreme to devise a system which will cost us untold millions of dollars in man-years to plug a possible minute loophole. The reason for my concern, and for my having performed the specific experiment outlined below, is the following:

Paragraph 52.22 (inventions and discoveries) as published in the Federal Register is covered in further detail in section 505 of the Grants Manual dated January 1, 1963. The first sentence of section 505, paragraph A, reads: "Department of Health, Education, and Welfare regulations (45 CFR, pts. 6 and 8) provide as a condition that all inventions arising out of the activities assisted by Public Health Service grants and awards *shall be promptly and fully reported to the Surgeon General.*" [Emphasis supplied.]

This report, according to paragraph C, must take the following form:

"C. FORMAL REPORTS OF INVENTION

"In respect to inventions reported direct to the Surgeon General for determination under Department regulations, a formal report of invention is required in the nature of answers to 18 questions listed in the outline for invention reports (exhibit 2). The form and other specific instructions for submission of the report will be provided upon request.

"Progress reports, which may include descriptions of inventions, may not substitute for formal reports of inventions."

In other words, in order to prevent the slight possibility that some other investigator may patent work performed by an NIH grantee, all possible discoveries or inventions should be reported to the Surgeon General, who will then decide whether patents should be taken out. If 10,000 to 20,000 publications are produced each year out of NIH-supported projects, the possibility then exists that the Surgeon General may wish to protect several thousand or perhaps all of them by patents. In order to be able to decide on this point, he must first have the necessary invention disclosures, which cannot be the usual annual reports of work performed under such grants.

NIH form PHS 3945 (dated March 1962, and now included in every new grant application form) defines an invention in the very broadest terms. In fact, these terms are so broad that, if the criterion of patentability is not left open to the individual investigator, a completely preposterous situation must arise. I shall cite one specific example: According to the present regulations, any invention or discovery (within the broad definition of PHS 3945)

would appear to present the Federal Government with many distasteful and difficult decisions which would be better left to the private sector if appropriate mechanisms can be developed.

Sincerely,

JOHN G. WELLES,
Head, Industrial Economics Division.

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., August 30, 1965.

HON. JOHN L. MCCLELLAN,
Senate Subcommittee on Patents,
U.S. Senate, Washington, D.C.

MY DEAR SENATOR MCCLELLAN: I hope that it is not yet too late to send you some comments on your proposed bill, S. 1809. Unfortunately, the complete text of this bill reached me only recently. I am sure that you have received numerous communications on the subject and I would like to limit myself to only three points which have some bearing on my professional competence. As a university professor, I have published several books and well over 500 scientific articles in the field of organic chemistry, largely on health-related subjects, and over half of this work has been supported partly or completely by grants from two Government agencies (National Institutes of Health and the National Science Foundation). I have also had, and still have, intimate connections with the pharmaceutical industry—having been a research chemist or director in two such companies prior to my academic career, and currently serving on the board of directors of one of these (Syntex Corp.). However, none of my university research is currently being performed in collaboration with any pharmaceutical company.

On the whole, I am very favorably impressed with your bill and am largely in agreement with what you are trying to accomplish. There are three points, however, where I believe that modifications will strengthen the bill and be of ultimate advantage to the public.

1. You draw no distinction between contracts and research grants. In universities, and especially in health-related areas, virtually all of the Government support is obtained in the form of grants rather than contracts. In section 3 (b) (1), your bill requires "the prompt and full disclosure by the contractor to that agency of any invention made in the course of or under the contract."

The NIH has already been operating theoretically under this assumption under their revised patent policy. In connection with its publication in the Federal Register, I wrote to the Surgeon General on July 24, 1963, indicating that such a requirement is totally unrealistic since it cannot be complied with and cannot be enforced. Many of the comments in that letter (especially pp. 2–4), of which I am enclosing a copy, also apply to section 3(b)(1) of your bill (every university scientist working under partial Government support is a "contractor") and I believe that an appropriate modification in the wording should be considered. Other than acknowledging receipt of that letter, I never did receive any reply from the Surgeon General. Senator Wayne Morse, with whom I once had some personal discussion during a plane trip on the general subject of Government support of academic research, had this letter and some related material republished in the Congressional Record (August 6, 1963, pp. 13434–13440, and especially pp. 13439–13440).

2. In section 4(a)(2), your bill reserves principal or exclusive rights to the Government in any invention made in the field of public health. While I sympathize with the motive, the result of this clause—if permitted to remain—will have precisely the opposite effect in that it will be to the disadvantage of the taxpaying public. I am making his rather blunt statement for the following reasons.

To my knowledge, during the past 10 years probably not a single important drug has been developed in an American Government or university laboratory and brought to approved human use through the FDA by such an agency or university. Under present FDA regulations (with which I agree), the possibility of such an event happening becomes virtually zero. I would estimate that, in the case of a new drug, it would cost an absolute minimum of half a million dollars, and frequently several millions, to satisfy all the FDA requirements for human use and for manufacture. No university has such money avail-

by some uninformed individual, because it is poor administration and ineffective procedure to have a regulation on the books which no one can follow. The only purpose I can see in it is that it now gives the Surgeon General a means of terminating a grant in "midair" by pointing out that a grantee has not followed an administrative regulation.

I recommend that the patent policy be simplified and adapted to the de facto situation:

(*a*) No patents are to be filed by any NIH grantee unless he proceeds in the manner outlined in the present patent policy (sec. 505(par. A).

(*b*) But, if the NIH grantee does not intend to file a patent application, no specific report should be required of him, his annual progress report and the eventual publications representing sufficient evidence that he has complied with the spirit in which the grant was made.

Yours sincerely,

CARL DJERASSI, *Professor of Chemistry.*

STATEMENT OF ROBERT C. ELDERFIELD

Mr. Chairman and distinguished members of the subcommittee, my name is Robert C. Elderfield and I appear before you today solely as an individual vitally interested in the future applications of such discoveries and inventions as may be forthcoming from our scientific and technological community to the general welfare of the people of the United States.

I am a professor of chemistry at the University of Michigan, a member of the National Academy of Sciences, a former chairman of the Division of Chemistry and Chemical Technology of the National Research Council-National Academy of Sciences, a member of the Board of Directors of the American Chemical Society and chairman of the American Chemical Society Board Committees on Education and Students, Grants and Fellowships, and International Activities. In the past I have served on various advisory panels and committees of the National Institutes of Health and am presently serving on three advisory boards to the Department of the Army. I am the author or coauthor of some 200 scientific papers and the holder of some 14 patents assigned to both private industry and various agencies of the Government. I have no connection with any industrial organization interested in the pending legislation.

Three bills are before your committee for consideration: S. 1899, introduced by Senator Long; S. 1809, introduced by Senator McClellan; and S. 789, introduced by Senator Saltonstall. I understand a fourth bill, S. 2326, introduced by Senator Dirksen, may also be considered by the subcommittee. While I have not studied this bill in detail, it appears to be in line with the philosophy expressed in my statement.

Previous testimony has amply documented the arguments against S. 1899 and I do not propose to belabor these. I intend, therefore, to confine my remarks to S. 1809 and S. 789. Furthermore, I shall limit my remarks to the application of the results of fundamental research subsidized in whole or in part by Federal funds in the universities of the country to the general benefit of the people of the United States.

Previous witnesses before you have emphasized the cost and the financial risks involved in the reduction of a laboratory "discovery or invention" to practice or, in other words, "development costs" in relation to "research costs." I should like to explore this phase of the problem a bit further with particular emphasis on matters affecting the public health, welfare, and safety of the American people. I believe that a strong case can be made for the argument that cooperation between university scientists and industry is capable of returning high yields for the benefit of the public in these areas.

Let us consider briefly the history of chloramphenicol ("Chloromycetin") as a prime example of the fruits of university-industry collaboration with resultant tremendous benefits to mankind. This material is one of the major antibiotics useful in treatment of typhoid fever, typhus, undulant fever, and many other infections. In 1947, Paul Burkholder, then professor of microbiology at Yale University, working under a pharmaceutical company grant, collected a soil sample in Venezuela, cultured this material, and sent it to the company for further testing. The powerful therapeutic activity of the antibiotic constituent was then discovered. This was followed by extensive development work at the

is done by a drug firm. This assumption is well founded, being based on my years of academic research where I was interested in having certain substances exposed to a wide pharmacological screening and found no Government or university laboratory equipped to do so. I still remember filing an NIH application more than 10 years ago on natural products from South American plants where the NIH study section inquired where the biological screening would be done. I indicated that I planned to send the substances to various drug firms such as Eli Lilly (a company with whom I had no formal connection whatsoever at that time, not even as a consultant) and this reply was considered entirely satisfactory by the NIH at that time. If I were to attempt to do this now, I would probably encounter great difficulty in locating any firm that would be interested in carrying out such screening.

Why can such screening not be done in university laboratories? It is possible to find investigators in pharmacology departments of certain medical schools who might be interested in testing compounds for a very specific type of biological action that they happen to be interested in, but I know of no such department in the United States or elsewhere where a broad biological screening for a wide variety of activities is performed. In fact, many of the best pharmacology departments in medical schools consider such work beneath them and are much more interested in studying the mechanism of action of known drugs or actually performing biochemical research. There is nothing wrong with this, since such work is very important, but it does not answer the question of where such screening can be performed in a university.

What about Government laboratories? Again, screening for certain activities can be done in certain Government laboratories, but general pharmacological screening for all types of potentially interesting biological and bacteriological activities is not available in any Government laboratory. If it were, I would be very interested to learn of it. About 10 years ago, while I was a professor at Wayne State University, I submitted various compounds to the NIH for testing in certain hormone assays (a specialized and very limited type of activity) and some of the results have come in to me only during the last 2 years. Frankly, I had already forgotten that I had ever submitted these substances. I am not citing this example as a criticism of the NIH. On the contrary, the NIH is fulfilling its real mandate very effectively and is playing an absolutely indispensable role in supporting most of the health-related basic research in American universities. Furthermore, a great deal of high-caliber intramural research is also being performed by scientists at the NIH. General pharmacological screening, however, is not one of the functions of the NIH and consequently is not done there to any extent, at least as far as I or many of my university colleagues are aware.

I have the impression that the new NIH patent regulations have virtually dried up this type of collaborative research between academic chemists and the pharmacological laboratories of drug firms. I believe that this is a pity, because there is little doubt that worthwhile drugs come out of such collaboration and that the one who suffers ultimately is the patient. The present provision (sec. 4(a)(2)) of S. 1809 is unlikely to change this state of affairs.

Yours sincerely,

CARL DJERASSI, *Professor of Chemistry.*

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., July 24, 1963.

DR. LUTHER TERRY,
Surgeon General, Department of Health, Education, and Welfare, U.S. Public Health Service, Bethesda, Md.

DEAR DR. TERRY: In your memorandum of June 12, 1963, addressed to all NIH grantees, you invited views and comments on the proposed research project grant regulations which appeared in the Federal Register in early June. This letter encompasses both comments and criticism on the present patent policy and I trust that it reaches you before the expiration of the 60-day deadline.

At the outset, I wish to emphasize that I am discussing only research grants and not research contracts. Furthermore, I would like to state that I am in complete agreement with the basic premise of the NIH patent policy; namely, that inventions made under partial or total NIH grant support should

That section 4(a)2, which applies substantially the same restrictions to the area of "public health, welfare, and safety" as are contained throughout the Long bill (S. 1899), be modified so as to provide in positive language adequate incentive to restore the past most fruitful collaboration between the university scientists and industry which at present has largely vanished. Such action could not but be most effective in making available to the public at large the benefits accruing from the heavy investment of public funds in matters of public health, welfare, and safety.

Specifically I would suggest that a given pharmaceutical firm be granted an exclusive license under either NIH-owned patents or preferably patent rights released by the Government administration by the grantee universities themselves on a new agent for a mutually agreed on term of years for recognition of its considerable contribution to the research and development effort involved as well as for the risk of its private capital. In return the company should use its best efforts to make such an agent promptly available to the public at a reasonable cost commensurate with the firm's investment of capital, facilities, and know-how.

In discussing such a policy with my colleagues I find differences of opinion as to the duration of the exclusive license. A good bit depends on the base point. If the period is calculated from the time a given drug is available for the market I would think a period of the order of 5 years would accomplish the objective. If it is based on the date of issue of the patent possibly 10 years should be considered. The 10-year term seems reasonable if it is kept in mind that some 5 years normally elapse between the discovery of a new agent and its availability to the public. The new FDA rules alone require some 3 years of clinical experience with an agent under close surveillance prior to its approval.

The disposition of "offshoot" patents arising from efforts by the firm and financed exclusively by the firm during the course of the development work warrants consideration. My feeling is that these should remain the property of the firm.

Adequate safeguards to insure prompt performance of the development work and to protect the public from exhorbitant prices should be part of the licensing agreement. These are probably met by the "march-in" provisions of the bills as they stand.

It is also important that all contract arrangements be concluded or clearly understood in advance of any participation by a firm.

Senator Saltonstall's bill (S. 789) accomplishes essentially these objectives. However, I believe, as indicated above, that the 3 years allowed for placing a new product in commercial use as given in section 6 is too short and should be roughly doubled at least in the case of new therapeutic agents.

From 1959 to 1964 the number of major new chemicals introduced yearly as prescription drug products declined from 63 to 17. While during the same time the aggregate yearly research and development expenditures of the pharmaceutical industry increased from about 190 million to about 300 million. Clearly this portrays a dramatic picture of increased costs in research and development with a corresponding decline in major new product introductions and underscores the need for a reasonable degree of market exclusivity.

It has also been estimated that the time spent on developing just one new, efficient drug, if only one person were involved in all study and research, would require 19 working years or 58,000 hours of the worker's life. This work and the attendant expenses in many cases is completely lost if the safety and efficacy of the drug is not demonstrated to the complete satisfaction of the Food and Drug Administration.

I submit that merely an investment of this magnitude in development of a single drug which is covered by a Government-owned patent provides ample justification for limited exclusive privileges for a cooperating company without considering the high failure rate in the development of chemicals into useful drugs. The alternative is for Government to assume these development costs. Otherwise advances made possible by federally sponsored research will remain on laboratory shelves indefinitely.

In conclusion, I should like to express my appreciation for this opportunity of presenting my views.

ELECTRONIC INDUSTRIES ASSOCIATION,
Washington, D.C., July 19, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: It is the purpose of this letter to supplement the statement transmitted to the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee in connection with the recent hearings relating to S. 789, S. 1809, S. 1899, and S. 1047. We hope that it will be helpful to your subcommittee if we supplement our prepared statement and add emphasis to matters raised by other witnesses at the hearings of June 1 and 2, and July 6 and 7.

We also have prepared a complete line-by-line recommendation for the convenience of your committee and staff. Since the line-by-line analysis of S. 1809 is all inclusive, regardless of relative importance, it is, so far as we are concerned, of no consequence that this additional paper become part of the record of the hearing of the subcommittee and it is offered only as a convenience.

There is one area where we would especially like to suggest thoughtful analysis. In testimony given on June 1, we heard discussions concerning the division of rights between the Government and between the contractors. In discussing the rights of Government, are we concerned with the right thing? Are we sometimes too close to the subject? Are the trees obscuring the forest?

The Government's needs, strictly speaking, have nothing to do with who holds title to an invention. Every Government need can be taken care of adequately with a license.

The public benefit is the key consideration and it does not follow automatically, in our opinion, that the public is best served when title is taken by the Government. We suggest that economic growth is our primary goal. New technology is very important to the achievement of that goal and many of us believe that that goal is reached best and fastest by leaving title, whenever possible, with the contractor who is responsible for the invention.

This is still a nation where the Government steps in only when non-Government can't or won't operate. The question was asked on the first day of the hearings, "Why does the contractor want title?" As a matter of law, title vests in an inventor or his assignee concurrently with the making of the invention. Hence, the contractor owns the invention upon its conception. Why does the Government want to deprive him of the invention? The Government does not take away the contractor's specially trained scientists. The contractor should retain title, under the principle stated above, unless there is a clear public interest superior to the contractor. Title in the contractor should therefor be disturbed as rarely as it is possible to do so. It can be argued that the public interest requires the taking of title only when the contractor won't or can't advance the technology.

A lot was said at the recent hearings about commercialization of inventions. We are sorry that so little was said of the importance of disclosure and yet disclosure is the primary purpose of the patent grant; i.e., the exchange of limited exclusivity for disclosure—not commercialization but disclosure. Some very valuable inventions may be commercially impracticable but they trigger off others which make commercialization feasible.

We wish to endorse the position taken at the hearings concerning the definition of "made" with respect to the making of an invention. The disposition of title to inventions should be based upon "conceptions" and should not sweep in reductions to practice. Industry was unhappy when the Department of Defense adopted this language years ago at a time when the Government received only a license and even then excluded the taking of such licenses when certain conditions were in existence. For example, suppose that modification is invented in electronic equipment. Its utility seems so obvious that the company involved does not rush to reduce it to practice or, perhaps, the inventor has tested the idea to his own satisfaction but has not yet demonstrated it and therefore has no corroboration. Now, suppose that a Government agency wishes to develop some apparatus and the invention previously conceived appears to be quite useful in fulfilling the work to be performed under the contract. Under section 4(a)(1), the contractor would lose title and yet the contractor has accomplished, at his own expense, everything except the final formal step. We do not believe that it is fair for the Government to deprive

the contractor of title in such a case. Suppose, further, that a contractor has spent hundreds of thousands of dollars of his own money in developing an idea practically to reduction to practice and then uses it for the first time in connection with a $50,000 contract. The contractor could, perhaps, very easily have avoided using the idea but, wishing to cooperate to the maximum with the Government he has applied his best technology in order to give the agency involved the best possible solution to its problem. Is it fair in such a case that the contractor lose title? We believe not. Hence, we believe that subject inventions should be limited to conceptions. If, on review of this matter, it is believed that some reductions to practice should be included within the definition, we respectfully submit that exceptions should be made when suitable equities are present.

Referring to section 3(b)(5), the determination of reasonable terms and conditions and, perhaps, the grant of compulsory licenses is placed in the hands of the agency involved. It seems to us that it may be advantageous from the Government's standpoint as well as from the public benefit point of view that the agency head do no more than supervise the grant of the licenses or be available as a "referee." In this manner, the burden of negotiating licenses would be transferred from the agency head to the contractor in an area where we believe the contractor would be more than happy to assume the burden and where the agency head is usually not best able to determine fair terms and conditions. There is no such thing in the area of licensing of the use of standard terms and conditions except in very limited situations. There is no substitute for depth of experience in a field to appreciate what is fair and workable and what is not. For example, what is a fair rate of royalty? What is the proper base to which the rate is applied? Should it be the entire apparatus furnished or only the proportionate part covered by the invention? What should be done about information, grant backs of rights possessed by the licensee, and improvements? Should the licensee or the licensor be required to police the patent or patents involved? On what grounds should the licensee or licensor be permitted to terminate the agreement? Should the licensee have the right to grant sublicenses? Should the licensee be required to exercise his best efforts in connection with the subject matter in order to maintain the license? Should the license be exclusive or nonexclusive? In almost every situation, the decision must be made on a case-by-case basis.

Referring to section 3(b)(8), we note that there is no excuse whatsoever permitted for failing promptly and fully to report an invention. In view of the serious penalty, i.e., forfeiture, involved and because reasonable men can well differ on reasonable time for reporting as well as whether reporting is required, we would urge insertion of the words "in bad faith." In support of the above suggestion, it is noted that conceptions and first actual reductions to practice form the basis for reporting of inventions. As a quick glance through board of interference and court decisions on interference situations will disclose, it is often difficult to determine when a conception has been made and when an actual reduction to practice has been made. Many interferences and court cases hinge on these determinations and, since there is usually involved a question of judgment with respect to which attorneys will differ, it is believed that a sort of "rule of reason" should be applied in this area and that severe penalties should not be enforced unless an element of fraud is present.

Referring to section 4(a), and more particularly to the criteria identified as justifying the taking of principal rights, there are certain ambiguities or at least certain degrees of indefiniteness which, in our opinion, are likely to cause future problems.

Referring to subparagraph (1), it would seem to us of doubtful value for the Government to acquire title to all inventions made merely because the invention may be required for use by governmental regulations or the public may become a user. In this connection, we would distinguish, for example, between a contract having as an object an improvement or cost reduction or some other minor modification of a well-known drug such as aspirin as distinguished from research directed to a significantly important medical advance such as a cancer cure. The same approach is applicable to subparagraph (2) where you might distinguish between an improvement in stair treads to minimize the danger of slipping as compared with a device for absolutely preventing collisions between vehicles. To soften the impact on contractors without disadvantaging the public, both of

these criteria might be restricted to improvements or inventions of critical significance in connection with the end objective. These problems are particularly serious for would-be contractors in drug and safety fields.

In section 4(a)(3), the Government may acquire greater rights whenever the invention "might" confer on the contractor a "preferred or dominant position." It can be argued and has been argued under the present DOD regulations that every patent confers a preferred position. Indeed, this is the purpose of the grant of a patent. It is not this sort of preferred position which you have in mind, we are sure, and, similarly, others who have proposed this type of language have not had this kind of dominance in mind. Therefore, it is believed that it would be helpful to reword this criterion as follows: "rights at the time of contracting is likely to confer on the contractor a dominant position;".

With respect to section 8(b), we would urge that a careful study be made because, at first thought, it appears to be repugnant to argue that the public benefit requires the taking of exclusive rights from the contractor only to, in turn, pass on those exclusive rights to another citizen or U.S.-based firm. It is for this reason that many believe that any citizen who wishes to use a Government-held patent should be entitled to a free, nonexclusive license. Both Saltonstall and Long propose dedication. We believe this approach is sound in most cases. In those cases where exclusivity is necessary for development, we believe exclusivity should remain with the contractor. The public interest can amply be satisfied by compulsory licensing.

Referring to lines 10 and 11 on page 15, the license provided therein may be granted with or without the payment of royalty to the United States. This type of language can lead to governmental regulation of industry by determining who can have a license and how much he may have to pay. It has been advocated, for example, that the Government grant exclusive licenses to a small company to help it grow larger and then when it is large enough to stand on its own feet, the license should be taken away and given to someone else or the royalty rate should be increased or some other step taken to remove any advantage it might have. Many fear this type of Government entry into the control of the business of the Nation.

Very truly yours,

T. L. BOWES,
Chairman, EIA Patents and Proprietary Information Committee.
GRAHAM W. MCGOWAN,
General Counsel, Electronic Industries Association.

SUGGESTED AMENDMENTS TO S. 1809

[Omit the part struck through and insert the part printed in italic]

A BILL To establish a uniform national policy concerning property rights in inventions made through the expenditure of public funds, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Inventions Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) The term "Government agency" includes any executive or military department of the United States, any other agency, independent commission, board, office, administration, or authority of the Government, and any wholly owned Government corporation.

(b) The term "agency head" means the head of any Government agency, except that (1) the Secretary of Defense shall be the agency head of the Department of Defense and of each military department thereof, and (2) in the case of any authority, commission, or other agency, control over which is exercised by more than one individual, such term means the body exercising such control.

(c) The term "contract" means any *written* contract, grant, agreement, commitment, understanding, or other *written* arrangement entered into between any Government agency and any other person where a *principal* purpose of the contract is the conduct of experimental, development, or research work. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract.

(d) The term "contractor" means any person and any public or private corporation, partnership, firm, association, institution, or other entity which is a party to the contract.

(e) The term "invention" means any invention, discovery, innovation, or improvement which appears to be reasonably patentable under title 35, United States Code.

(f) The term "disclosure" means a written statement sufficiently complete as to technical detail, *to the extent available,* to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation and, as the case may be, physical, chemical, or electrical characteristics of the invention.

(g) The term "made", when used in relation to any invention, means the conception ~~or first actual reduction to practice~~ of such invention ~~in the course of or~~ under the contract.

(h) The term "to bring to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine or system and, in each case, under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

CONTRACT REQUIREMENTS

SEC. 3. (a) Whenever any Government agency enters into any contract where a *principal* purpose is the conduct by a person of *a significant degree of* experimental, development, or research work, there shall be included in that contract provisions determined, under regulations which shall be promulgated by the head of that agency, to be effective to carry into effect the requirements of this Act.

(b) Each contract entered into by any Government agency shall contain provisions effective to—

(1) require the prompt ~~and full~~ disclosure by the contractor to that agency of any invention made in the course of or under the contract;

(2) reserve to the United States not less than an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice throughout the world, by or on behalf of the United States or by a foreign government pursuant to any treaty or other agreement with the Government of the United States *in force at the time the contract is entered into,* of each such invention;

(3) reserve to the contractor not less than an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention *together with the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded.* Such license shall extend to its existing and future associated and affiliated companies, if any, within the corporate structure of which the contractor is a part and shall be nontransferable, except that it shall be assignable to the successor of that part of the contractor's business to which such invention pertains;

(4) reserve to the United States such greater rights in each such invention as the head of that agency may determine in conformity with the provisions of this Act;

(5) provide, in the case of the issuance to any person other than the head of that agency of the principal or exclusive rights in any invention, appropriate means whereby such agency head thereafter may require the owner of those rights to grant to other persons licenses for the practice of such invention, upon such reasonable terms and conditions *subject to review by the agency head at the request of either party to the negotiation* ~~as the agency may prescribe~~ upon a determination made by such agency head, after affording the opportunity of a hearing to the owner of those rights, that (a) the owner of those rights has not *within three years after issuance of the patent* exerted substantial efforts to bring the invention to the point of practical application and (b) the public interest would be *better* served by *requiring the owner to license one or more* ~~the issuance to~~ other persons ~~of licenses for the~~ *to* practice ~~of~~ that invention;

(6) provide, in the event the principal ~~or exclusive~~ rights in any invention are acquired by the head of that agency on behalf of the United States, and such agency head does not *timely* elect to secure a patent in a foreign country, appropriate means whereby the contractor may *timely* file and retain such greater foreign rights, subject to the rights reserved to the United States in subsection (b)(2) of this section;

(7) provide, in the event a patent application is filed on any invention made by the contractor, appropriate means whereby the applicant shall be required to include within the first paragraph of the specification of such application and any patent issuing thereon, a statement specifying that the invention described therein shall be subject to the provisions of this Act;

(8) provide, in the event the contractor does not make a prompt ~~and full~~ disclosure *to the extent reasonably possible* to that agency of any invention made ~~in the course of or~~ under the contract, appropriate means whereby any rights of the contractor in such invention shall be void and such rights shall become the exclusive property of the head of that agency, on behalf of the United States, upon a determination made by such agency head, after affording the opportunity of a hearing to the contractor, that the contractor knowingly *and in bad faith* withheld rendering a prompt and full disclosure to that agency of such invention; and

(9) provide that nothing contained in this Act shall be construed as requiring the granting to the United States of any right or interest duly acquired in or with respect to any patent issued for any invention not made ~~in the course of or~~ under the contract.

PROPERTY RIGHTS OF *THE CONTRACTOR AND* THE UNITED STATES

SEC. 4. (a) The agency head ~~shall~~ *may* acquire, at the time of entering into the contract, on behalf of the United States, the principal ~~or exclusive~~ rights in any invention made by the contractor if:

(1) the purpose of the contract is to create, *or* develop, ~~or improve~~ *new* products, processes, or methods which are intended for commercial use by the general public, or which will be required for such use by governmental regulations *provided that such products, processes, or methods are of critical significance and that no reasonably competitive item is readily available*; or

(2) the purpose of the contract is for exploration into fields which directly concern *and are of critical significance in connection with* the public ~~health,~~ *health* ~~welfare,~~ *welfare* or safety; or

(3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been *substantially* the *sole* ~~sole, principal, or prime~~ developer of the field, and the acquisition of exclusive rights at the time of contracting ~~might~~ *is likely to* confer on the contractor a ~~preferred or~~ dominant position; or

(4) the services of the contractor are for the operation of a government-owned research or production facility, or for coordinating and directing the work of others.

In exceptional circumstances the contractor may *retain* ~~acquire~~ at the time of contracting or upon disclosure of the invention, *notwithstanding the existence of any of the conditions specified in section 4(a) (1) to (4), inclusive,* greater rights than the nonexclusive license specified in section 3(b)(3) if the agency head *determines* ~~certifies~~ that such action will best serve the public interest.

(b) ~~Where~~ *Notwithstanding the provisions of section (4)(a), where* the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the Government, and the work called for by the contract is in a field of *science or* technology in which the contractor has acquired technical competence directly related to an area in which he has an established nongovernmental commercial position, the agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after the invention has been identified, that there are *exceptional* ~~special~~ circumstances which indicate that the public interest would suffer as a result of the contractor retaining the principal or exclusive rights in such invention.

(c) As to any other contract executed under this Act that is not within the purview of subsections (a) and (b) ~~(c)~~ of this section, the determination of rights in any invention made by the contractor shall be made by the agency head after the disclosure required by section 3(b)(1) has been received. Upon receipt thereof, the agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after examination of the facts of the particular case, that there are ~~special~~ *exceptional* circumstances which indicate that the public interest would suffer as a result of the contractor acquiring the principal or exclusive rights.

In exceptional circumstances the determination of such rights may be made at the time of contacting, if the agency head certifies that such action will best serve the public interest.

ADMINISTRATIVE PROCEDURES FOR DETERMINATIONS

SEC. 5. (a) Whenever a contract provides the agency head with the right to acquire, after the invention has been identified, greater rights than the nonexclusive license specified in section 3(b)(2) and and he decides to exercise such rights, he shall within sixty days after receipt of the disclosure required by section 3(b)(1):

(1) make a determination supported by findings of fact, that he shall acquire on behalf of the United States greater rights than the nonexclusive license specified in section 3(b)(2) pursuant to the provisions of section 4(b) or section 4(c);

(2) if the agency head determines that he shall acquire on behalf of the United States greater rights than the nonexclusive license specified in section 3(b)(2), he shall within sixty days after making such determination transmit to the contractor written notice of his intention which notice shall—

(A) specify the nature of the property right in that invention which the agency head claims on behalf of the United States;

(B) state with particularity the basis for belief that the United States is entitled under this Act to acquire such property right in that invention; and

(C) accord to the contractor, or his duly authorized representative, an opportunity for a hearing, conducted in compliance with the provisions of the Administrative Procedure Act, upon the question whether the United States is entitled under this Act to acquire such property rights in that invention.

(b) If no application for a hearing under section 5(a)(2)(C) is made by the contractor, or his duly authorized representative, within thirty days after receipt of notice by the contractor, or if the agency head determines upon the record of any such hearing that the United States is entitled under this Act to acquire greater rights than the nonexclusive license specified in section 3(b)(2), the agency head shall issue with respect to that invention a written declaration of acquiring on behalf of the United States which shall—

(1) identify with particularity the invention to which it relates; and

(2) specify the nature of the property right therein so acquired on behalf of the United States. Such declaration shall be served upon the contractor or upon his duly authorized representative, and a copy thereof shall be transmitted to the Commissioner of Patents. The agency head shall advise the Commissioner of Patents promptly concerning the pendency and result of any judicial review of such declaration.

JUDICIAL REVIEW OF DETERMINATIONS

SEC. 6. (a) Whenever *an agency head acquires the principal rights under section 4(a), or* any such declaration of acquiring is issued by an agency head after hearing, or any final determination is made under section 3(b)(5) *or section 3(b)(8)*, any party aggrieved thereby shall be entitled to a judicial review of the basis for such declaration or final determination by filing a written petition for an order setting aside that declaration or determination in the United States Court of Appeals for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides and serving a true copy of the petition upon the agency head, within sixty days after notice of such declaration or determination. The agency head thereupon shall certify and file in the court a true and correct transcript of the entire record of the proceedings upon which the *acquisition*, declaration or determination was based, including all evidence taken and the findings and conclusions made by the agency head thereon.

(b) The court shall have jurisdiction to hear and determine any such petition, and shall have power to affirm, modify, or set aside the *acquisition*, declaration or determination. In any such review, the findings of fact made by the agency head, if supported by substantial evidence, shall be conclusive. If either party shall

apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material, the court may order such additional evidence to be taken by the agency head and to be considered in such manner and upon such terms and conditions as the court may deem proper. The agency head may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file such modified or new findings, and recommendations, if any, which, if supported by substantial evidence, shall be conclusive with respect to action in the matter under consideration. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

(c) Any declaration of acquiring or determination issued under this Act shall become final—

(1) upon the expiration of the time allowed for the making of application for an administrative hearing under this Act, if no such application is made within that time by the recipient of notice given under section 5(a) or by his duly authorized representative; or

(2) upon the expiration of the time allowed for filing a petition for judicial review, if no such petition has been duly filed within such time; or

(3) upon the expiration of the time allowed for filing a petition for certiorari if the order of the agency head has been affirmed or the petition for judicial review has been dismissed by a United States court of appeals, and no petition for certiorari has been duly filed; or

(4) upon the denial of a petition for certiorari, if the order of the agency head has been affirmed or the petition for review has been dismissed by a United States court of appeals; or

(5) upon the expiration of ten days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the order of the agency head be affirmed or that the petition for review be dismissed.

INTERIM EXAMINATION OF PATENT APPLICATION

SEC. 7. Whenever the agency head makes a declaration of acquiring in accordance with the provisions of this Act, if he concludes that such invention may contain patentable subject matter, he may file with the Commissioner of Patents a patent application covering said invention, unless one has been filed by the contractor, even though such declaration of acquiring has not become final as provided in section 6 of this Act. The Commissioner of Patents shall examine such application, but shall not issue any patent thereon until he has been notified by the agency head that such declaration has become final, *in which case the patent shall issue to the Government as assignee,* or that a final determination has been made that the United States is not entitled to any rights greater than the nonexclusive license specified in section 3(b)(2) *in which case the patent shall issue to the inventor or his assignee.* The Commissioner of Patents shall proceed as provided in title 35, United States Code, except that nothing contained therein shall preclude a party who has successfully contested a declaration of acquiring from exercising all rights with respect to the securing of a patent on such invention that said party would have enjoyed if there had been no declaration of acquiring by the agency head.

PATENTS OF THE UNITED STATES

SEC. 8. (a) Whenever an agency head has taken title to any invention by declaration of acquiring which has become final or by authority of any other provision of this Act, and he has reason to believe that such invention is patentable, he may make application to the Commissioner of Patents for the issuance of a patent therefor to such agency head on behalf of the United States. If the Commissioner determines that such invention is patentable, he shall issue to such agency head on behalf of the United States a patent therefor. ~~Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.~~

(b) Each agency head may grant an *appropriate* ~~exclusive or non-exclusive~~ license for the practice of any invention for which he holds a patent acquired under this Act on behalf of the United States. Any such license shall be granted under such terms and conditions as the agency head shall determine to be in the public interest. Any such license may be granted for the effective period of the patent or for a more limited period of time, and may be granted with or without the payment of royalty to the United States.

REPORTS TO THE CONGRESS

SEC. 9. The head of each agency which awards any contracts of the class described in section 3(a) shall submit semiannual reports to the Congress containing—

(a) the number of contracts executed for each of the subsections (a), (b), and (c) of section 4, and the number of inventions disclosed pursuant to such contracts;

(b) the number and general nature of such inventions with respect to which the agency acquired no greater rights than a royalty-free license in accordance with section 4, and a summary of the findings of fact upon which such determinations were made; and

(c) the number and general nature of such inventions with respect to which the agency has acquired greater rights than a royalty-free license in accordance with section 4 *and a summary of the findings of fact upon which a determination of the applicability of section 4 was based.*

SEVERABILITY CLAUSE

SEC. 10. If any provision of this Act, or the application of such provision to any person or circumstance, is held invalid, the remainder of this Act or the application of such provisions to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

TECHNICAL AMENDMENTS

SEC. 11. (a) Section 10(a) of the Act of June 29, 1935, as added by section 101 of the Act of August 14, 1946 (60 Stat. 1085, as amended; 7 U.S.C. 427i(a)) is amended by striking out the following language: "Any contracts made pursuant to this authority shall contain requirements making the results of research and investigations available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine."

(b) The National Science Foundation Act of 1950 is amended by striking out section 12 thereof (42 U.S.C. 1871).

(c) The Atomic Energy Act of 1954 is amended by striking out section 152 thereof (42 U.S.C. 2182).

(d) The National Aeronautics and Space Act of 1958 is amended by—

(1) striking out section 305 thereof (42 U.S.C. 2457); and

(2) by striking out in section 306 "the Inventions and Contributions Board, established under section 305 of this Act," and inserting in lieu thereof "an Inventions and Contributions Board which shall be established by the Administrator within the Administration."

(e) The Coal Research and Development Act of 1960 (74 Stat. 336) is amended by striking out section 6.

(f) The Helium Act Amendments of 1960 (74 Stat. 918) is amended by striking out the following language in section 4: "*Provided, however,* That all research contracted for, sponsored, cosponsored, or authorized under authority of this Act shall be provided for in such a manner that all information, uses, products, processes, patents, and other developments resulting from such research developed by Government expenditure will (with such exceptions and limitation, if any, as the Secretary may find to be necessary in the interest of national defense) be available to the general public: *And provided further,* That nothing contained herein shall be construed as to deprive the owner of any background patent relating thereto to such rights as he may have thereunder."

(g) The Saline Water Conversion Act of 1961 (75 Stat. 628) is amended by striking out section 4(b).

(h) The Arms Control and Disarmament Act of 1961 (75 Stat. 631) is amended by striking out section 32.

(i) The Water Resources Research Act of 1964 (78 Stat. 329) is amended by striking out section 303.

(j) The Appalachian Regional Development Act of 1965 (79 Stat. 20) is amended by striking out section 302(d).

EFFECTIVE DATE

SEC. 12. This Act shall take effect on the first day of the fourth month beginning after the date of enactment of this Act.

GENTEX CORP.,
Carbondale, Pa., July 23, 1965.

CHAIRMAN, SENATE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS,
Washington, D.C.

DEAR SIR: In reporting prior proceedings of the Patents Subcommittee of the Senate Judiciary Committee remarks were attributed to you which indicated a greater concern on your part for the ethical implications in patent infringement than for possible material losses.

I am in complete accord with your viewpoint, and in a long history of contention with various Government groups, this has been our precise position.

The appropriation of data either before or after a patent is issued, when submitted in confidence or when confidence is clearly implied, constitutes, in my belief, an appropriation of intellectual property.

The fact that a material loss may be involved is incidental to the larger issue which you have cited. The practice is not isolated, is not unimportant. We believe that it is a violation of proper business practice.

As president of Gentex Corp., I desire in this context to present to you a brief résumé of some of this corporation's experience with the Department of Defense, particularly in relation to the appropriation of intellectual property.

We make this presentation as responsible citizens and in the belief that the best interests of the country will be served by frank discussion. We believe that there should be sincere evaluation of the impact the appropriation of intellectual property has on technological progress and on the patent system.

During the past quarter of a century the Gentex Corp. has been principally involved in developing products of military interest. All of our developments have been privately funded. No Government moneys have been used.

The Gentex Corp. has over 200 issued and pending patents. Most of these developments have been put to military usage. We have devised and developed the designs, presented the concept or product, and secured very few contracts for our efforts in these developments. This has been particularly so since World War II.

While we present the experience of a single company, it is reasonable that the same experiences could be recited by other companies. Still others may have had their intellectual property appropriated and then, being discouraged, discontinued submitting ideas.

There is no substitute for private and encouraged effort to achieve a high rate of technological progress. Technological progress is most economically obtained by the encouragement of private initiative. This is the foundation of our democratic system and upon which system this country grew strong and great.

The Gentex Corp.'s background is that of a company which has over the years been oriented to meeting military requirements. Corporate policy is that of using its own funds to finance the risks of development with the logical expectation that subsequent production would permit recovery, with profit, for the risked capital.

During World War II, we had the privilege of developing and producing, or only developing, solely with our own funds, the complete parachute assembly on the following assignments: The dropping of mines; the resupply of pigeons; the sonobuoy for locating submarines; drop sonde for securing weather data over inaccessible areas; essential cargo work for the Office of Strategic Services; the atomic bomb as dropped over Nagasaki and Hiroshima.

These were among our assignments. According to the best information available, there was not one single reported failure in a military operation. In accord with our own records, approximately 98 percent of our required raw materials were in the noncritical class.

During the post-World War II period we were the first to develop very high altitude parachutes for meteorological rockets, and proved their feasibility. We have had extensive experience in designing critical helmets for military aviators, as well as shrapnel-resistant helmets as used by tank crewmen. Our work includes the sturdy cross-slot webbing now used for cargo nets, safety equipment such as a carrier for live detonators, advanced heat-reflective clothing material, and other survival equipment.

It is discouraging to have created and developed intellectual property and to then have it appropriated.

We have presented our cases to administrative authorities. It is very unfortunate that the rationale of justification is more important than the determination of right.

We were encouraged, for example, on a crash basis, to develop a survival kit container for the Department of the Navy.

This item fitted into the framework of company policy in that it was for military usage. It was in an area of our technical competence and experience, and we could reasonably hope to produce the item on our present facilities. The Department of Defense was apparently to be the sole customer.

The requirement was urgent and deliveries were stated to be needed within 45 days after the award of a contract. It was agreed that Gentex would act only as a subcontractor, and would not submit a direct proposal as a prime contractor. The Gentex part number or equal was in the specification submitted with the invitation.

The prime contractor proceeded to reverse engineer the item after the award of the contract. The Navy then did three things:

1. The prime contractor was permitted to submit several prototypes, each of which reverse engineered our design. This was in violation of the Armed Services Procurement Regulations covering articles of brand name or equal. The material used was approximately one-fourth as costly as that which we found necessary to use to achieve proper function. The Navy's own specification drawn at a later date confirmed our determination for the use of the same expensive material.

2. The 45-day delivery requirement was extended more than 6 months to accommodate the prime contractor's desire to attempt to reverse engineer.

3. The contract was amended approximately 3 months after its award, without a reduction in price, to include a patent indemnity clause which would protect the Navy against a Gentex patent, should one thereafter be issued. (The clause employed was unusual in that it dealt not with patent indemnity generally, but singled out the Gentex Corp. specifically.)

The rationalization by administrative authorities for this action was that:

(1) There was then no valid issued patent.

(2) Gentex had sold a single container to the Department of Defense, which was not in fact so; that the Department therefore had the right to reverse engineer or to permit it to be reverse engineered.

(3) The prime contractor believed that he could make the article at less cost than we had quoted, and he was therefore entitled to reverse engineer it, even though performance under the contract was greatly delayed.

(4) Absence of consideration to the Government, despite the extended delivery and the known substitution of inexpensive material, was not considered relevant.

(5) Both the Navy and Gentex had been too informal in detailing of rights to intellectual property which might arise, and without any apparent regard to the extreme urgency and short term for performance of the program.

The correspondence is voluminous. (See exhibit 1.)[1]

Gentex developed an improved sound attenuating earcup for helmets which would permit the earcup to be oriented to the axis of the ear of the wearer.

The article was first submitted in small experimental quantities as a proprietary item to the Radio Corp. of America. The Radio Corp. of America submitted a drawing to the Air Force clearly marked that it was propietary to Gentex Corp. (General Textile Mills, Inc.)

The Department of the Air Force appropriated the design, transferred it to their own drawings, and asserted that they had a right to it in view of a contract they had with Radio Corp. of America. We protested this action several times verbally at a high administrative level.

[1] Contained in committee files.

We also included the earcup in two complete helmets submitted in confidence solely for evaluation to the Department of the Air Force. The special features of which helmets were clearly outlined in writing.

The Air Force subsequently asserted they had procured the design from Protection, Inc. This was, however, 2 years later than our experimental submission to Radio Corp. of America. The Air Force subsequently also asserted that they had secured the design from the Roanwell Corp. The matter is now before the Comptroller General. A copy of the protest to the Comptroller General is attached. (Exhibit 2)[1]

In the fields of protective helmets, parachutes, cargo nets, heat reflective material, carriers of live detonators, the story seems to be the same—creation, submission, acceptance, appropriation.

During the past year, the Department of Defense has issued a series of Defense procurement circulars which attempt to clarify the rights of inventors to intellectual property. There appears to be much confusion and lack of appreciation of these policies at the working level, perhaps in part because of the failure of these circulars to reach the root of the problem.

We have been told that we should not disclose an idea to anyone in the Department of Defense without a contract covering that disclosure. That the disclosure should not even be made to the contracting officer until after such a contract has been signed. This is obviously a condition which is impossible to fulfill.

In the light of this interdiction, however, the Office of General Counsel, Department of Defense, negotiated an agreement with us on behalf of the Department of the Navy, Bureau of Supplies and Accounts. The Bureau would not execute the agreement to effect a contract, despite pressure stated to have been exerted by the Office of General Counsel.

The agreement was to cover the test and evaluation of a superior heat reflective fabric which we had developed. The failure of the Bureau of Supplies and Accounts to enter into the agreement in accordance with the stipulations established by the Department of Defense precluded consideration of the item. The failure did underscore the impracticality of attempting to comply with the procedure regarded as essential to the protection of intellectual property.

We subsequently submitted the same heat reflective fabric to the Department of the Air Force, which they then permitted to be reverse engineered. The garment manufacturer who was the prime contractor under the Defense Clothing and Textile Supply Center, used our pricing, for ours was the only product available to the stated specification at the time of the original and even subsequent openings of the proposal under the invitation.

This reverse engineering, as with the survival kit, produced a product which was inferior. In order to make deliveries under the contract acceptable, the essential performance requirements for resistance to abrasion were lowered by 60 percent on the reverse engineered product. This reduction in quality level was without any apparent material consideration to the Government.

The preceding presentation details our experience in three specific instances.

Department of Defense policy with respect to patents and rights in data is, however, reflected in letters dated October 10, 1963, and October 23, 1963, attached hereto as exhibit 3.[1] These letters, between Gentex and the Honorable R. Tenney Johnson, then Deputy General Counsel of the Army, crystallize the issues involved. The corespondence is a discussion of a Department of Defense policy statement on matters of patent and intellectual property.

Briefly, there are three basic issues:

(1) That any appropriation of property rights by the Department of Defense is a violation of ethics and of rights guaranteed under the Constitution;

(2) That the purchase of a product resulting from a privately funded development by the Department of Defense does not of itself confer the right to the intellectual property which made such production possible;

(3) That quotations from nonpatent holders were frequently lower than those reecived from patent holders, even when the Department of Defense made allowance for reasonable royalties. It is pointed out that the royalty allowance is arbitrary, as selected by the Department of Defense without an analytical determination of its adequacy. Consideration is not given to the factors of risk, expense of development, or other pertinent elements of cost.

[1] Contained in committee files.

The letters also discuss suggested procedural and policy changes.

The National Security Industrial Association recently held a series of nationwide briefing conferences, one of which was in New York on March 16 and 17, 1965. Every speaker for the Department of Defense stressed interest in receiving suggestions for development programs, with the concurrent statement that if the submitted program was of interest it would be funded by the Government. No interest was expressed for the submission of privately funded developments.

It appears self-evident that ideas which were only in the embryonic form would be submitted to the Department. Ideas would not be submitted for Government funding which had already been reduced to practice at the expense of the developer, and where the rights to related intellectual property would be entangled.

Economy in development work is obtained by many inventors, each working in his own field, creating progress in a sound, effective, economical, and democratic way. The inventors should be encouraged to present their ideas and products to any or many interested groups with confidence that their right to their intellectual property would be respected.

There is no present court or parajudicial court to review disputes arising out of violation of rights to intellectual property. An administrative settlement is slow and largely ineffective. Our own experiences have been poor and long delayed. The Office of the Comptroller General has little authority if any. The Armed Services Board of Contract Appeals has no authority, for invariably there is no contract existing covering the matter in question. A suit in the Court of Claims is long, involved, expensive, disconcerting, and few can afford the time, the dislocation of their normal effort, and the expense, considering the risk which is involved.

I did suggest to Congressman Emanuel Celler the creation of a parajudicial board patterned after the Armed Services Board of Contract Appeals, to hear matters involving the violation of intellectual property and other matters with the Department of Defense.

The practice of appropriation denies much of the fruits of further independent research and product improvement to the Government. The independent inventor, having once had his property appropriated, is reluctant to make further submissions. Improvements to the basic invention by the inventor who, by basic experience in the project is best qualified to make improvements, are therefore denied the Government.

The reduction of a device or improvement to practice invariably suggests improvements to the inventor. Grounded as he is in the basic elements of the design, these improvements are likely to be much more significant than are those which suggest themselves to one merely interested in appropriating by reverse engineering.

Gentex has continued to make submissions of inventions and product improvements only on a very selective basis. These submissions are made only to agencies where there is an expectation that our rights to the device or improvement will be protected. This is the Gentex experience and practice, but there are undoubtedly many other companies who, faced with the same problem, have either handled it as we have or have followed the policy of complete withholding of information.

Drying up the sources of progress is not the way this country's interests are best served. The country has grown strong by encouraging and rewarding productive effort. The denial of encourgement and reward can only destroy the historic basis of this country's progress. This we believe should be a matter of great concern to responsible legislative and administrative authorities.

Very respectfully submitted.

LEONARD P. FRIEDER, *President.*

GENERAL ELECTRIC CO.,
New York, N.Y., June 18, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, Washington, D.C.

DEAR SENATOR MCCLELLAN: I am writing you to express my personal views, and those of the General Electric Co., concerning pending legislative proposals respecting Government patent policy. I respectfully request that this letter be included in the record of the current hearings on these matters.

No company has a longer history of successful collaboration with its Government in respect to research and development for the national defense than does

General Electric Co. From its vital work in submarine detection in World War I to its equally vital roles in the development of radar, jet engines, and atomic energy in and after World War II, its cooperation with Government in the national interest has been continuous. Where national security has been at stake, contracting procedure has been given second place to meeting the national need. For example, during World War II, countermeasure equipment to jam radar detected on Japanese torpedo bombers was delivered within 9 days of the Government's request—obviously without regard to fine points of contractual paperwork.

In reviewing results at one of the company's plants during the war period, Secretary of the Navy, Frank Knox, made the statement: "No single industry in America has made a better response, a quicker response, to our appeal for help than General Electric. I don't think what you've done here can be duplicated anywhere in the world."

However, in a time when future governmental contracting policy is being studied—as it should be—through open congressional hearings, we believe it both proper and desirable that we state such views as our experience in Government research and development work has given us respecting patterns of contracting which we consider to be in the public interest.

As general manager of the Atomic Products Division of the General Electric Co. during the early postwar period, and as vice president-engineering of the company since 1960, I have had a deep interest in, and concern with, both the background matters referred to above and the issues discussed below.

I am familiar with the approaches represented by the several bills pending before the Senate's Patent, Trademark, and Copyright Subcommittee in its current hearings and believe that the preferred approach to solution is to be found in S. 1809. I construe this bill as one which places maximum reliance on private development of inventions while recognizing areas of special national interest which may require a measure of public control.

Patents are pieces of property, just like land and buildings, on which venture businesses are built. Patents in the public domain are just like any other public property—people don't build businesses on them. It is very true that some public land and some public buildings are needed—society, as a whole, uses them. But patents are different—they are either used for business purposes or not at all—by anyone.

Government itself has no need for the exclusionary powers afforded by patents. Government does not need power to exclude others from using inventions, nor would its doing so in any way advance the governmental objectives in funding research and development, the work of Government, or the public interest.

Research for itself does no good. The results of research do good when they show the way to goods or services that soviety values. Much research can only resut in showing that certain materials or equipment, if made available, would be useful. Privately owned patents can be incentive to business to make them available.

Although some minor part of results of Government-funded research and development may be readily usable in commercial products and services, it is usually the case that much more money and effort is required to develop an invention for commercial use than is spent in the original research. Extensive product and market development, including engineering development, testing, evaluation, and marketing effort, are essential to move these items into the commercial marketplace, and it is essential that private risk capital be attracted to accomplish these difficult and speculative tasks. Public funds and resources should rarely be used to undertake this kind of commercial risk venture.

As President Kennedy said in his statement of Government patent policy: "The public interest in a dynamic and efficient economy requires that effort be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiative to this end and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under Government contracts."

In my understanding, the underlying philosophy and approach of S. 1809 (and of S. 789), as in the case of the Kennedy policy, is to permit private contractors to retain limited commercial rights wherever such rights are likely to provide needed incentive to call forth risk capital for the further development and utilization of technology. I believe this to be the keystone of an effective and

dynamic Government patent policy, and for this principal reason favor S. 789 and S. 1809 over S. 1899.

I note that S. 1809 (as well as the other bills presently under consideration) provide that any exclusive rights retained by any contractor in any invention made in the performance of Government research and development are conditional on affirmative action taken by the contractor to develop the invention for commercial uses. Thus, the public interest is protected, and unless a contractor actually does respond to the patent incentives and applies private risk capital to these ends, the invention can be opened up to others who may.

I recognize that an acceptable patent policy must protect the public interest by seeing that private rights are not retained where such rights would frustrate either governmental contracting objectives or important considerations of public intereset. S. 789 and S. 1809 seek to accomplish this by specifying contracting situations in which the Government shall normally acquire principal or exclusive rights in inventions made in such situations. In the interest of flexibility S. 1809 then provides that the contractor may acquire greater rights than a nonexclusive license in such situations if the agency head certifies that such action is in the public interest. I believe that this is a sound approach and endorse it. I suggest, however, that some clarification of the guidelines may be useful to the administrator and the contractor alike.

First, I note the special interest and importance of the so-called cost sharing situation—the situation in which a Government contract requires work to be done which is only partially funded by the Government. I take it that there is general agreement that there are frequently contractor equities in such cases that would indicate contractor retention of more than simply a nonexclusive license and suggest that some specific recognition of this principle be included in the wording of S. 1809.

A special class of invention that I believe deserves differential treatment is that which the Kennedy policy calls nonprimary object inventions. The basic approach of defining contracting situations in which the Government will normally acquire principal rights to all contract-originated inventions assumes that most or all such inventions will be directly associated with the contract objective—the desired end product—and essential to the objective. This is far from the case. Although, hopefully, there are inventions of this type in each major development program, there are frequently secondary inventions—a temperature measuring device or a metal strengthening process, for example—that were used only incidentally in arriving at the desired end result and are by no means essential to duplicating that result in the future. It is these off-the-mainstream inventions that often show the greatest potential for commercial application. However, they most often need incentives to attract risk capital to bring this about. I, therefore, urge that provision be made for allotting the contractor primary rights in respect to this class of invention, regardless of what is done with "primary-purpose" inventions.

Related to the suggestion just made, there is perhaps not enough definition in S. 1809 of the "principal or exclusive rights" which the Government would acquire in certain cases. Do these terms necessarily equate to complete domestic and foreign title in the Government subject only to a nonexclusive license to the contractor? It seems undesirable to think in terms so completely black and white. Specifically in regard to the many inventions that will be made having multiple uses, the Government could appropriately acquire principal rights in its primary field of interest—agriculture or civil defense, for example—while at the same time permitting the contractor to retain limited exclusionary rights in other fields, thus affording an incentive to bring about further development, testing, etc., to put this technology to work in new fields.

Although I understand that it has been referred to in your current hearings, I believe that the importance of the interrelationship between Government patent policy and foreign trade can hardly be overemphasized. Since World War II, new and developing industries are emerging around the globe, and with improved transportation and communications, these industries are competing in a worldwide marketplace. The effects of this global competition are beginning to be felt dramatically in terms of the balance-of-payments problems confronting this Nation. President Johnson's export expansion program is a significant recognition of the importance of the ability of American industry to successfully compete in the worldwide marketplace in relation to our national welfare. The protection that the patent systems of all major industrial countries afford to cre-

ators and developers of technology will be an increasingly important factor in this growing international competitive struggle. If the representatives of American industry are to have maximum leverage in this struggle, it is important that they not be deprived of the asset of patent protection in foreign countries.

For these reasons I believe that, almost without regard to the allocation of U.S. rights in contract-connected inventions, disposition of foreign rights should normally be left in the hands of private contractors. Necessary safeguards in terms of compulsory licensing in situations involving essential international interests of the U.S. Government could readily be provided for.

I believe that with revisions related to the above suggestions, S. 1809 would well serve the public interest of the United States. I endorse the balanced and flexible approach which S. 1809 represents and hope for its enactment into law.

We appreciate this opportunity to express our views on this subject. If we can aid the subcommittee in pursuing this matter further we would be pleased to do so.

Sincerely yours,

FRANCIS K. MCCUNE, *Vice President.*

HAZELTINE CORP.,
Little Neck, N.Y., July 1, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
U.S. Senate, Washington, D. C.

DEAR SENATOR MCCLELLAN: For years we have anxiously listened to the intense debates on Government patent policy which have culminated in S. 789 (Saltonstall), S. 1809 (McClellan), and S. 1899 (Long), now before your committee. We think it imperative that the issue be brought to an early conclusion in order that the harmful uncertainty in industry be ended.

Before commenting on the three bills, permit us to outline our philosophy.

To us it is erroneous to assume that because the Government expends funds in research and development contracts with us, it is the father of resulting inventions. Such inventions are the outgrowth of our 40-odd years' accumulation of skills, experience, and investment in electronics, a field in which we are an acknowledged leader. We think it quite fair that our Government partner receive a nonexclusive license, but no more, because the intellectual property is basically ours—the creation of the brainpower of our skilled technical staff, which we alone train, support, and encourage with private risk capital.

All agree with the Government's desire to have inventions put to actual use. After all, that is the purpose of the patent system. But we believe this can best be accomplished by preserving our freedom to exploit for profit inventions which are, in any event, our own creation. As prudent managers of our stockholders' interests, we are very reluctant to risk capital in developing an invention if we do not have the shield of patents unhampered by fear of Government seizure. True, we will do it without patents if the gamble is a good one, but we will do it more, often with unencumbered patents. And make no mistake about it—considerable risk is involved in further research, product development, and marketing, after an invention is made, to put the invention in use by the public. We do not believe you are going to find businessmen as eager to take these risks where the patents are in a Government portfolio.

The history of our company is very much germane to the subject. Professor Hazeltine left Government service at the end of World War I with an idea on how to apply defense technology to the then-embryonic domestic radio receiver market. The company was formed around him and grew to its present size in the intervening years, during which it contributed extensively to the commercialization of domestic radio, monochrome, television, and, finally, color television. Out of this grew extensive contributions to defense electronics. Patents were an extremely important part of the business; it is quite probable that it never would have developed without them.

Despite what Senator Long is said to have testified, the patents, in practical effect, were the result of many millions of dollars of Hazeltine's own risk capital, not the Government's. Senator Long obviously does not have the facts. Of our present portfolio of about 500 U.S. patents, very few were the offshoot of work under Government contracts and only because our people were able to use our prior skills in the Government projects. Of the latter, none played any substan-

tial role in the success of the company's patent program. There was no lack of effort to promote them, but for various practical and commercial reasons, the effort did not succeed. Moreover, licenses under them have always been available to anyone who thought he could succeed.

Under the circumstances, we strongly urge the passage of your S. 1809. We would prefer to see it strengthened in certain areas to make more certain our unencumbered right to inventions, which are really the result of our own experience, know-how, and capital. We would be pleased to offer specific suggestions for amendment, should you so desire.

As to S. 1899, we think it fundamentally erroneous in philosophy and a serious danger to healthy development of inventions in the public and private interest.

Respectfully,

L. B. DODDS, *Vice President.*

INDUSTRIAL NUCLEONICS CORP.,
Columbus, Ohio, July 16, 1965.

Subject: Senate bill 1809.

Senator MCCLELLAN,
Chairman, Senate Judiciary Committee, Subcommittee on Patents, Trademarks, and Copyrights, Washington, D.C.

DEAR SENATOR MCCLELLAN: I regret that my schedule did not permit me to testify before your committee. I have, however, prepared a statement, in the appropriate number of copies, which I would like included as part of the record of the hearing on Senate bill 1809.

I would appreciate receiving a copy of the hearing testimony.

Sincerely,

HENRY R. CHOPE,
Executive Vice President.

STATEMENT OF HENRY R. CHOPE, EXECUTIVE VICE PRESIDENT, INDUSTRIAL NUCLEONICS CORP., COLUMBUS, OHIO

On behalf of Industrial Nucleonics Corp. of Columbus, Ohio, I am pleased to have this opportunity to present this statement for consideration by the Senate Subcommittee on Patents, Trademarks, and Copyrights. This statement is submitted in connection with Senate bill 1809 (McClellan), proposing a uniform national policy with respect to inventions resulting from Government-funded research and development.

We believe that the establishment of a uniform Government patent policy is important and will have far-reaching effects on the American economy. We believe that a properly worded statement of legislative intent and policy is needed to implement and expand the President's memorandum on Government patent policy dated October 10, 1963, and that most of the provisions of S. 1809 are appropriately directed to protection of the public interest without stifling free enterprise. I am therefore making this statement on behalf of Industrial Nucleonics Corp. in general support of the McClellan bill.

Our company is perhaps unique in making use of a new family of materials developed entirely at Government expense—namely, artificial radioisotopes developed and sold by the Atomic Energy Commission for use in commercial electronic measurement and control systems developed almost entirely at private expense by American industry. We hope that a brief history of the development and products of our company, and a brief statement of some of our recent specific problems in seeking to help Government agencies take advantage of our experience and know-how without compromising our background rights in inventions and technical data, may provide a case history helpful to this subcommittee.

INDUSTRIAL NUCLEONICS CORP.

Our company was formed only 15 years ago in Columbus, Ohio, by three young engineering-science graduates—of which I was one—with very little capital or prior business experience. By dint of hard work, good fortune, and some private financial backing, our company has very recently grown out of the "small business" category. We presently have approximately 600 employees of whom over one-fourth hold engineering or scientific college degrees.

Our investments in research and development have averaged almost $1 million per year since the founding of the company and are currently running at over $2 million per year. Practically all of this R. & D. investment has come out of company funds without Government support.

Our company is a pioneer in the practical commercial application of atomic energy to peaceful industrial uses. We design, manufacture, sell and service a large family of precision radiation gaging and control systems especially adapted to meet widely varying requirements of the material-processing industries. We have installed well over 7,000 gaging and control systems, employing radioisotopes, in such basic material-processing industries as rubber, paper, plastics, tobacco, steel, and chemicals. Our products, sold under the trademark "AccuRay," combine principles of nuclear physics, advanced electronics and servomechanism theory to provide extremely precise measurement and control of moving materials being processed or chemicals flowing in pipes without contacting or touching the materials being processed. For example, some of our gages measure the thickness variations in extremely thin, plastic sheets, such as are used for food wrapping and packaging, and control the sheet profile to tolerances measured in microinches at commercial process speeds. Others of our systems precisely control the sheet thickness of heavy steel sheet traveling at hundreds of feet per minute and almost instantly detect abnormalities that might cause severe damage to the steel-rolling equipment. Others of our gages measure densities of liquid or dry chemicals in pipes with accuracies of better than 1 percent or precisely determine the fill-level of materials in bottles or cans on high-speed conveyor lines.

All this has been made possible by utilizing radioisotopes made available by the AEC for commercial uses, without significant Government financing or support. In fact, the Government has only recently come to our company to take advantage of our technology developed at our private expense.

Patents have played an important part in protecting our substantial private R. & D. investment. Our U.S. patent portfolio hos now grown to about 120 issued patents with over 100 patent applications pending. Accordingly, our company is very much concerned with Government policy and administrative procedures concerning rights to inventions developed under Government contract. We would like to help Government agencies make use of our know-how but, under the widely varying policies and procedures of various Government agencies, we find it difficult to assure that our commercial rights in our patents and technical data will not thereby be jeopardized. We have particular difficulty in dealing with the AEC because of statutory requirements and the AEC's restrictive patent and data policies. These problems are also present, in varying degrees, in dealing with the National Aeronautics and Space Agency, the Federal Aviation Agency and various branches of the Department of Defense. Some of these problems cannot at present be completely resolved by the individual Government agency because of statutory requirements; others are created by nonstatutory departmental policies. We hope that a few specific examples of recent problems in dealing with these Government agencies with respect to inventions and technical data will serve to point up the need for a more effective, though flexible, Government patent policy which will help us in dealing with any Government agencies who may seek our services.

PRESENT PRACTICES OF VARIOUS GOVERNMENT AGENCIES ON PATENT RIGHTS

You are intimately familiar with the present diversity in practice of the Government agencies and departments with regard to patent rights. It would appear helpful, however, to review briefly these practices to see how they affect a company in the position of Industrial Nucleonics Corp. which is particularly interested in developments relating to atomic energy and has acquired special capabilities in this field, almost entirely without sponsorship by the U.S. Government.

Industrial Nucleonics Corp. has had an unusual opportunity to experience in actual situations the current attitudes and practices of various Government agencies on patent rights. In fact, within the past 2 years, Industrial Nucleonics has negotiated with each of the Navy, Air Force, NASA, and the AEC, and contracts have been obtained from these agencies or departments. I will refer to specific examples of the practice of these departments by using the actual lan-

guage of the contract. A complete copy of the patent provisions for each of the listed contracts is found in appendixes I to V.

A. Navy Department

On June 23, 1964, Industrial Nucleonics Corp. entered into a contract with the Department of Navy, Bureau of Naval Operations (contract No. NOw 64–0551–f) for the study of various nuclear techniques to measure the corrosion of a metal coated with paint. This study involved the use of considerable background technology developed by Industrial Nucleonics Corp., including equipment and know-how. The contract patent provisions (see appendix I) provided that Industrial Nucleonics could obtain an exclusive license to any inventions conceived or made under the contract, with a nonexclusive, free license to the Government. Such a study contract conceivably opens the door to the private files of our company and is very dangerous to accept without some positive incentives. The contract provided the necessary incentive by holding out the opportunity to utilize the information and inventions developed for commercial equipment. Industrial Nucleonics accepted certain undesirable aspects of the contract, because of the protection which would be afforded on inventions which could have commercial use.

B. Department of Air Force

On June 25, 1963, Industrial Nucleonics Corp. entered into a contract with the Department of Air Force, Rome Air Development Center (contract No. AF 30 (602)—3123) for the evaluation of a system for tracking a missile during launch. The system had been conceived by Industrial Nucleonics Corp. prior to the contract and involved the use of nuclear techniques. Patent applications were filed before the contract on several inventions relating to missile lift-off measurement. The contract patent provisions (see appendix II) made no reference to background rights; i.e., a license to the Government in these inventions irrespective of whether they were first actually reduced to practice under the contract. Inventions developed under the contract were reported and the patent provisions provided that an exclusive license would be granted to us, with a license to the Government. The incentive for offering our inventions to the Government for possible first actual reduction to practice under a further contract was that inventions resulting from the initial contract and other contracts would be available, protected by an exclusive license, for commercial development. Again, Industrial Nucleonics Corp. utilized a great deal of its technical know-how and equipment to perform the initial contract. The Government had to come to Industrial Nucleonics Corp. not only for the technical know-how but for the inventions that could have solved their problem.

C. National Aeronautics and Space Administration

On June 24, 1964, Industrial Nucleonics Corp. entered into a contract with the National Aeronautics and Space Administration (contract No. NAS 8—11736) to evaluate the effectiveness of cryogenic propellant tank vent systems operating under or near zero-gravity conditions. This contract called for a wide range study of techniques for solving the problem, with specific emphasis on the applicability of nuclear measuring devices. Our special technology and know-how in this field was the reason for our receiving the contract. As a result of the contract, several inventions were conceived and reported to the Government. We are pleased to have been able to continue the work under a new contract through Douglas Aircraft, sponsored by NASA.

The inventions conceived under this contract may have commercial applications. Industrial Nucleonics realized the potential value of the developments. The patent provisions (see appendix III) provided for a petition of waiver of rights, which has been filed by Industrial Nucleonics Corp. for each of the inventions. Without this opportunity to obtain commercial rights, it is seriously doubted whether our corporation would have assumed such a small contract (about $18,000) to reveal all of the techniques and knowledge that we could muster to solve the Government's problem. It was the incentive for development of a commercial system that caused us to feel the advantages of outweighted the disadvantages, primarily due to the favorable patent provisions. It is our understanding that NASA is reasonable in its granting of such a waiver and our hope is that our corporation qualifies for it. We believe our company should qualify, if any corporation in the United States can qualify.

D. Atomic Energy Commission

On or about June 1965, Industrial Nucleonics Corp. obtained a development contract with the Atomic Energy Commission (contract No. AT (11–1)—1471) for study of the use of nuclear techniques and systems for maintaining helicopters in a desired formation. We had submitted a proposal to the AEC which suggested several possible systems. Apparently the AEC was quite impressed with our proposal and, obviously, the need for such a system is very great, in view of presently inadequate systems for maintaining helicopters in formation in bad weather.

The contract was preceded by long and strenuous negotiations with the AEC concerning patent rights. At times our judgment suggested that we should not accept a research and development contract from the AEC, in view of unfavorable patent provisions. Initially, the AEC people gave us little hope that concessions could be made as far as patent rights were concerned, in view of AEC's policies of obtaining background license rights as well as all title and rights to inventions related to atomic energy. Since this experience was our first encounter with the AEC, we were a little uncertain as to how the patent provisions would affect our company.

The patent provisions (see app. IV) which were eventually obtained clearly show how the AEC is unable, under present patent policies, to promote the development of nuclear technology and systems for commercial applications. Under the contract, Industrial Nucleonics first had to grant to the Government a background license in all inventions which were made before the contract and in any way involved in the contract work. Obviously, this provision raised a serious danger for us in guiding our engineers as to what to embody in the contract work. The AEC certainly could not expect us to use all the background technology we have. Consequently, the Government had the risk of receiving less than it might have obtained under a more favorable contract arrangement.

Another aspect of the contract, not so apparent to us at first, was the fact that Industrial Nucleonics would not be able to obtain an exclusive license for commercial use in any inventions useful in the field of atomic energy. This means that our company, basically devoted to the development of atomic energy applications, cannot under present policies and statutes realize exclusive patent rights to inventions arising out of work performed under AEC contracts for use in the field of atomic energy. Certainly, this leaves small incentive for any company with sizable private technology to deal with the AEC. More serious, from the viewpoint of the public interest, is the fact that the AEC is unable to realize greatest benefits from industry's potential contributions.

In this particular AEC contract, the "type C" patent provision was very carefully worded so that we obtained an exclusive license only in inventions "inherently capable of a use other than in the production or utilization of nuclear material or atomic energy." Unraveling this language: we could obtain an exclusive license only as to inventions outside our primary field of commercial interest. Further, such license was limited to the use of the invention "for applications other than use in the production or utilization of special nuclear material or atomic energy."

It is quite apparent that whatever exclusive license rights are obtained under the present "type C" AEC patent provisions, they are of very little value to a company in our commercial position.

E. Federal Aviation Administration

While our company has not yet obtained a contract with the FAA, it has presented several bid proposals. It is our understanding that the FAA follows AEC practices very closely. This fact has caused us some reservations in following up possible FAA contract opportunities. In addition, the FAA informed us by letter of May 12, 1956 (see app. V), that it would not accept any proposal for evaluation if marked with a "proprietary data" stamp. This has caused us further restraint in submitting any ideas to the FAA, since it is our normal policy to maintain a confidential status for the subject matter, to prevent creating a statutory bar. Other Government agencies do not appear to have this restrictive disclosure practice.

Summary of present patent rights distribution, as a contractor in the atomic energy field views it

Department or agency	Background rights to Government	Inventions made or conceived under contract	
		In atomic energy field	Other fields
Navy (DOD)	None, unless specially negotiated.	May receive exclusive license.	May receive exclusive license.
AF (DOD)	Same as above	Same as above	Same as above.
AEC	Required	No rights	May receive exclusive license.
NASA	None, unless specially negotiated.	Can petition for waiver of rights.	Can petition for waiver of rights.

ANALYSIS OF SENATE BILL 1809

We have carefully studied Senate bill 1809. It seems to resolve many of the difficulties we have experienced in working with the Government and in providing full support, using our substantial private technology. One reason why this bill meets with our favor is that the patent practice of each of the Government agencies would be placed on the same basis, yet with some flexibility.

As pointed out above, the AEC is completely different in its present approach and this has seriously affected our ability to contract with the AEC. We respectfully submit that the present AEC patent policies have hampered the development of atomic energy for commercial applications. S. 1809 appears to follow substantially the present patent practices of NASA and to provide some flexibility in a contract negotiation, depending on the circumstances. Hence, we generally support S. 1809.

PUBLIC BENEFIT DERIVED FROM PATENT PRACTICE INSTITUTED BY SENATE BILL 1809

We submit that the public will benefit by the adoption of S. 1809, especially in the field of atomic energy. As pointed out above, it is presently not possible for a company with substantial private technology and private inventions to work effectively with the AEC without giving up some of its own rights, especially if the subject matter has commercial applications.

In the alternative, some companies may take contracts from the Government, yet not use their best efforts, since certain private technology would be withheld to prevent granting a license to the Government, or making a disclosure of proprietary data to the Government. Of course, the risk of public disclosure of data is always present when dealing with the Government; but the possibility of obtaining exclusive rights to commercial developments can, in some instances, outweigh the disadvantages of such disclosure. We believe that developments in the field of atomic energy would be much more likely to get into the hands of the public under a more favorable AEC patent policy. Senate bill 1809 permits equitable contract arrangements which would encourage companies, such as ours, to work with the Government and ultimately make available to the public the byproducts of such work.

I thank you for the opportunity to present this information to your committee and I certainly would be glad to supplement any points where further information is necessary.

BIOGRAPHICAL SKETCH OF HENRY R. CHOPE, COLUMBUS, OHIO

Henry R. Chope was born in Louisville, Ky. He studied mathematics and science at the University of Louisville and was graduated from the Ohio State University in electrical engineering. He holds advanced degrees in engineering sciences and applied physics from both California Institute of Technology and from Harvard University.

During World War II, Mr. Chope served in the Armed Forces, specializing in development and use of electronic and radar equipment for meteorological

purposes and upper-air radiation research. He participated in many field experiments and tests, including radiation measurements in connection with the atomic tests at Bikini Atoll.

Mr. Chope was a founder and is presently executive vice president of Industrial Nucleonics Corp., Columbus, Ohio, which company was the first to specialize in industrial applications of atomic energy for on-line process measurement and control. He holds some 25 issues or pending U.S. patents in the fields of electronic and nuclear measurement, automatic controls, computers, and data processing, as well as numerous corresponding foreign patents.

He is a senior member of the Institute of Electrical and Electronic Engineers, of the Instrument Society of America, and of the American Institute of Industrial Engineers. He has membership in the American Nuclear Society, the American Association for the Advancement of Science, Tau Beta Phi, Beta Kapa Nu, and the Ohio and National Societies of Professional Engineers. Mr. Chope also participates as a member of the Labor-Management Committee of the Atomic Energy Commission, the Ohio Atomic Energy Advisory Board, and various committees of industry associations concerned with science, technology, and patents.

APPENDIX I

A. As used in this clause, the following terms shall have the meanings set forth below:

(i) The term "subject invention" means any invention, improvement, or discovery (whether or not patentable) conceived or first actually reduced to practice either—

(*a*) in the performance of the experimental, developmental, or research work called for or required under this contract; or

(*b*) In the performance of any experimental, developmental, or research work relating to the subject matter of this contract which was done upon an understanding in writing that a contract would be awarded: *Provided*, That the term "subject invention" shall not include any invention which is specifically identified and listed in the schedule for the purpose of excluding it from the license granted by this clause.

(ii) The term "technical personnel" means any person employed by or working under contract with the contractor (other than a subcontractor whose responsibilities with respect to rights accruing to the Government in inventions arising under subcontracts are set forth in (g) and (h) below), who, by reason of the nature of his duties in connection with the performance of this contract, would reasonably be expected to make inventions.

(iii) The term "subcontract" and "subcontractor" mean any subcontract or subcontractor of the contractor, and any lower tier subcontract or subcontractor under this contract.

B(1). The contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, and royalty-free license to practice, and cause to be practiced by or for the U.S. Government, throughout the world, each subject invention in the manufacturers, use, and disposition according to law, of any article or material, and in the use of any method. Such license (i) shall be nontransferable, except that the Government shall have the right to grant sublicenses to any foreign government or international organization specifically for use in programs established by international agreements for research, development, or production of weapons or equipment for mutual defense, and (ii) shall include the practice of subject invention in the manufacture, use, and disposition of any article or material, in the use of any method, or in the performance of any service acquired by or for the Government or with funds derived through the military assistance program of the Government or otherwise through the Government.

And the contractor hereby assigns to the Government all the rights that the contractor would have to enforce the subcontractor's obligations for the benefit of the Government with respect to subject inventions. If there are no subcontracts containing patent rights clauses, a negative report is required. The contractor shall not be obligated to enforce the agreements of any subcontractor hereunder relating to the obligations of the subcontractor to the Government in regard to subject inventions.

(i) The contractor recognizes that the Government, or a foreign government with funds derived through the military assistance program or otherwise through the U.S. Government, may contract for property or services with respect to which the vendor may be liable to the contractor for royalties for the use of a subject invention on account of such a contract. The contractor further recognizes that it is the policy of the Government not to pay in connection with its contracts, or to allow to be paid in connection with contracts made with funds derived through the military assistance program or otherwise through the U.S. Government, charges for use of patents in which the Government holds a royalty-free license. In recognition of this policy, the contractor agrees to participate in and make appropriate arrangements for the exclusion of such charges from such contracts or for the refund of amounts received by the contractor with respect to any such charges not so excluded.

NOTE.—Patent provisions of contract No. NOw 64-0551-f (Navy).

APPENDIX II

A. As used in this clause, the following terms shall have the meanings set forth below:

(i) The term "subject invention" means any invention, improvement, or discovery (whether or not patentable) conceived or first actually reduced to practice either—

(*a*) in the performance of the experimental, developmental, or research work called for or required under this contract; or

(*b*) in the performance of any experimental, developmental, or research work relating to the subject matter of this contract which was done upon an understanding in writing that a contract would be awarded; provided that the term "subject invention" shall not include any invention which is specifically identified and listed in the schedule for the purpose of excluding it from the license granted by this clause.

(ii) The term "technical personnel" means any person employed by or working under contract with the contractor (other than a subcontractor whose responsibilities with respect to rights accruing to the Government in inventions arising under subcontracts are set forth in (*g*) and (*h*) below), who by reason of the nature of his duties in connection with the performance of this contract, would reasonably be expected to make inventions.

(iii) The terms "subcontract" and "subcontractor" mean any subcontract or subcontractor of the contractor, and any lower tier subcontract or subcontractor under this contract.

B (1). The contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, and royalty-free license to practice, and cause to be practiced by or for the U.S. Government, throughout the world, each subject invention in the manufacture, use, and disposition according to law, of any article or material, and in the use of any method. Such license (i) shall be nontransferable, except that the Government shall have the right to grant sublicenses to any foreign government or international organization specifically for use in programs established by international agreements for research, development, or production of weapons or equipment for mutual defense and (ii) shall include the practice of subject invention in the manufacture, use, and disposition of any article or material, in the use of any method, or in the performance of any service acquired by or for the Government or with funds derived through the military assistance program of the Government or otherwise through the Government.

(2) With respect to:

(i) Any subject invention made by other than technical personnel; and

(ii) Any subject invention conceived prior to, but first actually reduced to practice in the course of, any of the experimental, developmental, or research work specified in (a) (i) above;

the obligation of the contractor to grant a license as provided in (b) (1) above, to convey title as provided in (d) (ii) (B) or (d) (iv) below, and to convey foreign rights as provided in (e) below, shall be limited to the extent of the contractor's right to grant the same without incurring any obligation to pay

royalties or other compensation to others solely on account of said grant. Nothing contained in this patent rights clause shall be deemed to grant any license under any invention other than a subject invention.

C. The contractor shall furnish to the contracting officer the following information and reports concerning subject inventions which reasonably appear to be patentable:

(i) A written disclosure promptly after conception or first actual reduction to practice of each such invention together with a written statement specifying whether or not a U.S. patent application claiming the invention has been or will be filed by or on behalf of the contractor;

(ii) Interim reports at least every 12 months, commencing with the date of this contract, each listing all such inventions conceived or first actually reduced to practice more than 3 months prior to the date of the report, and not listed on a prior interim report, or certifying that there are no such unreported inventions; and

(iii) Prior to final settlement of this contract, a final report listing all such inventions including all those previously listed in interim reports.

D. In connection with each subject invention referred to in C(i) above, the contractor shall do the following:

(i) If the contractor specifies that a U.S. patent application claiming such invention will be filed, the contractor shall file or cause to be filed such application in due form and time; however, if the contractor, after having specified that such an application would be filed, decides not to file or cause to be filed said application, the contractor shall so notify the contracting officer at the earliest practicable date and in any event not later than 8 months after first publication, public use, or sale.

(ii) If the contractor specifies that a U.S. patent application claiming such invention has not been filed and will not be filed (or having specified that such an application will be filed thereafter notifies the contracting officer to the contrary), the contractor shall:

(*a*) Inform the contracting officer in writing at the earliest practicable date of any publication of such invention made by or known to the contractor or, where applicable, of any contemplated publication by the contractor, stating the date and identity of such publication or contemplated publication; and

(*b*) Convey to the Government the contractor's entire right, title, and interest in such invention by delivering to the contracting officer upon written request such duly executed instruments (prepared by the Government) of assignment and application, and such other papers as are deemed necessary to vest in the Government the contractor's right, title, and interest aforesaid, and the right to apply for and prosecute patent applications covering such invention throughout the world, subject, however, to the rights of the contractor in foreign applications as provided in (e) below, and subject further to the reservation of a nonexclusive and royalty-free license to the contractor (and to his existing and future associated and affiliated companies, if any, within the corporate structure of which the contractor is a part) which license shall be assignable to the successor of that part of the contractor's business to which such invention pertains;

(iii) The contractor shall furnish promptly to the contracting officer on request an irrevocable power of attorney to inspect and make copies of each U.S. patent application filed by or an behalf of the contractor covering any such invention;

(iv) In the event the contractor, or those other than the Government deriving rights from the contractor, elects not to continue prosecution of any such U.S. patent application filed by or on behalf of the contractor, the contractor shall so notify the contracting officer not less than 60 days before the expiration of the response period and, upon written request, deliver to the contracting officer such duly executed instruments (prepared by the Government) as are deemed necessary to vest in the Government the contractor's entire right, title, and interest in such invention and the application, subject to the reservation as specified in D(ii) above; and

(v) The contractor shall deliver to the contracting officer duly executed instruments fully confirmatory of any license rights herein agreed to be granted to the Government.

E. The contractor, or those other than the Government deriving rights from the contractor, shall, as between the parties hereto, have the exclusive right to file applications on subject inventions in each foreign country within:

(i) Nine months from the date a corresponding U.S. application is filed;

(ii) Six months from the date permission is granted to file foreign applications where such filing had been prohibited for security reasons; or

(iii) Such longer period as may be approved by the contracting officer.

The contractor shall, upon written request of the contracting officer convey to the Government the contractor's entire right, title, and interest in each subject invention in each foreign country in which an application has not been filed within the time above specified, subject to the reservation of a nonexclusive and royalty free license to the contractor together with the right of the contractor to grant sublicenses, which license and right shall be assignable to the successor of that part of the contractor's business to which the subject invention pertains.

F. If the contractor fails to deliver to the contracting officer the interim reports required by (c) (ii) above, or fails to furnish the written disclosures for all subject inventions required by (c) (i) above shown to be due in accordance with any interim report delivered under (c) (ii) or otherwise known to be unreported, there shall be withheld from payment until the contractor shall have corrected such failures either ten (10) percent of the amount of this contract, as from time to time amended, or $5,000, whichever is less. After payment of 80 percent of the amount of this contract, as from time to time amended, payment shall be withheld until a reserve of either 10 percent of such amount, or $5,000, whichever is less, shall have been set aside, such reserve or balance thereof to be retained until the contractor shall have furnished to the contracting officer:

(i) The final report required by (c) (iii) above;

(ii) Written disclosures for all subject inventions required by (c) (i) above which are shown to be due in accordance with interim reports delivered under (c) (ii) above, or in accordance with such final reports, or are otherwise known to be unreported; and

(iii) The information as to any subcontractor required by (h) below.

The maximum amount which may be withheld under this paragraph (f) shall not exceed 10 percent of the amount of this contract or $5,000, whichever is less, and no amount shall be withheld under this paragraph (f) when the amount specified by this paragraph (f) is being withheld under other provisions of this contract. The withholding of any amount or subsequent payment thereof to the contractor shall not be construed as a waiver of any rights accruing to the Government under this contract. This paragraph (f) shall not be construed as requiring the contractor to withhold any amounts from a subcontractor to enforce compliance with the patent provisions of a subcontract.

G. The contractor shall, unless otherwise authorized by the contracting officer as hereafter provided, include a patent rights clause containing all the provisions of this patent rights clause except provision (f) in any subcontract hereunder of $3,000 or more having experimental, developmental, or research work as one of its purposes. In the event of refusal by a subcontractor to accept such a patent rights clause, the contractor (i) shall promptly submit a written report to the contracting officer setting forth the subcontractor's reasons for such refusal and other pertinent information which may expedite disposition of the matter, and (ii) shall not proceed with the subcontract wihout the written auhorization of the contracting officer. Reports, instruments, and other information required to be furnished by a subcontractor to the contracting officer under the provisions of such a patent rights clause in a subcontract hereunder may, upon mutual consent of the contractor and the subcontractor (or by direction of the contracting officer) be furnished to the contractor for transmission to the contracting officer.

H. The contractor shall, at the earliest practicable date, notify the contracting officer in writing of any subcontract containing one or more patent rights clauses; furnish the contracting officer a copy of each of such clauses; and notify the contracting officer when such subcontract is completed. It is understood that with respect to any subcontract clause granting rights to the Government in subject inventions, the Government is a third party beneficiary; and the contractor hereby assigns to the Government all the rights that the contractor would have to enforce the subcontractor's obligations for the benefit of the Government with respect to subject inventions. If there are no subcontracts containing patent rights clauses, a negative report is required. The contractor shall not be obli-

gated to enforce the agreements of any subcontractor hereunder relating to the obligations of the subcontractor to the Government in regard to subject inventions. (i) The contractor recognizes that the Government, or a foreign government with funds derived through the military assistance program or otherwise through the U.S. Government, may contract for property or services with respect to which the vendor may be liable to the contractor for royalties for the use of a subject invention on account of such a contract. The contractor further recognizes that it is the policy of the Government not to pay in connection with its contracts, or to allow to be paid in connection with contracts made with funds derived through the military assistance program or otherwise through the U.S. Government, charges for use of patents in which the Government holds a royalty-free license. In recognition of this policy, the contractor agrees to participate in and make appropriate arrangements for the exclusion of such charges from such contracts or for the refund of amounts received by the contractor with respect to any such charges not so excluded.

NOTE.—Patent provisions of Contract No. AF 30(602)-3123 (Air Force).

APPENDIX III

A. As used in this clause and in the property rights in inventions clause of this contract, the following terms have the meanings assigned:

(i) "Reportable item" means any invention, discovery, improvement or innovation, whether or not the same is susceptible of protection under the U.S. patent laws, which is made in the performance of work under this contract or in the performance of any work done upon an understanding in writing that this contract would be awarded;

(ii) "Made" means conceived or first actually reduced to practice, and "making" means conceiving or first actually reducing to practice;

(iii) "Invention" means any reportable item which appears to fall within a statutory class of patentable subject matter (35 U.S.C. 101 and 171) and which has a reasonable possibility of being patentable;

(iv) "Subcontract" and "subcontractor" means any subcontract or subcontractor of the contractor, and includes any lower tier subcontract or subcontractor under this contract;

(v) When this clause and the property rights in inventions clause are included in any subcontract, "contractor" shall be read as "subcontractor" and "contract" shall be read as "subcontract";

(vi) "Person" means any individual, partnership, group, corporation, association, institution or other entity; and

(vii) "Administrator" includes the Administrator of NASA and his duly authorized representative.

B. The contractor shall conduct a continual review of the results of the work performed under this contract for the purpose of identifying reportable items and shall furnish promptly to the contracting officer a written report concerning each reportable item. Such report shall include:

(i) Such technical detail as is necesary to identify, describe, and convey an understanding of the nature, purpose, operation, and physical (electrical, chemical, etc.) characteristics of each reportable item;

(ii) A designation of each reportable item considered by the contractor to constitute an invention;

(iii) A statement which sets forth the relationship of each reportable item to the present contract work; and

(iv) A statement of all apparent uses in which each reportable item may find application.

C. In addition to the report required in (b) above, the contractor shall furnish to the contracting officer within 1 month following each semiannual anniversary date of this contract a summary of the review activities undertaken and the results thereof which shall include:

(i) A written report as required by (b) above for each reportable item not previously reported;

(ii) A statement listing each subcontract containing this reporting of new technology clause and the property rights in inventions clause, stating the name, and address of each subcontractor, describing the work to be performed, and giving the estimated completion date of each subcontract.

D. After completion of the contract work and prior to final payment, the contractor shall furnish a report:

(i) Listing all reportable items or certifying that there were no reportable items; and

(ii) Confirming or correcting previous information submitted regarding subcontracts, or certifying that no such subcontracts were awarded.

E. (1) In each subcontract hereunder involving research, experimental, design, engineering, or development work, the contractor shall include the property rights in inventions clause of this contract and this clause, except for paragraph (f) below.

(2) In each subcontract hereunder of over $50,000 which calls for work of the type described in (e) (1), the contractor shall, prior to tendering final payment:

(i) Obtain from an official having authority to execute such subcontract on behalf of the subcontractor, a letter certifying compliance by the subcontractor with this clause and the property rights in inventions clause of this contract; and

(ii) Submit a copy of such letter to the contracting officer.

(3) In the event of refusal by a subcontractor to accept this clause and the property rights in inventions clause or either of them, the contractor shall promptly notify the contracting officer of such refusal and shall not execute the subcontract in question until provisions have been approved in writing by the contracting officer for inclusion in said subcontract.

F. (1) Except as provided in subparagraph (2) below, if the contractor fails to comply with the provisions of this clause or of the property rights in inventions clause of this contract, there shall be withheld from payment, until such failures have been corrected, either 10 percent of the amount of this contract, or $50,000, whichever is less. After payment of 85 percent of the amount of this contract, as from time to time amended, payment shall be withheld until a reserve of either 10 percent of such amount, or $50,000, whichever is less, shall have been set aside, such reserve or balance to be retained until the contractor shall have complied with the provisions of this clause and the property rights in inventions clause as aforesaid. In the event that the contractor does not comply with the provisions aforesaid within 1 year after final payment (exclusive of the amount withheld) of this contract, any amount actually withheld under the provisions of this contract and authorized to be withheld under this paragraph (f) shall be deemed to be liquidated damages for noncompliance with this clause. No amount shall be withheld under this paragraph (f) so long as the amount specified in this paragraph (f) is being withheld under other provisions of this contract. The payment of any amount or withholding thereof under this paragraph (f) shall not be construed as a waiver of any rights accruing to the Government under this contract.

(2) Subparagraph (1) does not apply when the contract is a no fee contract with an educational institution. In no fee contracts with nonprofit institutions other than an educational institution, the percentage amount specified to be withheld in subparagraph (1) above is reduced from 10 percent to 1 percent.

G. The Government may duplicate, use, and disclose in any manner and for any purpose whatsoever, and have others so do, all reports required by paragraphs (b) and (c) of this clause.

23. PROPERTY RIGHTS IN INVENTIONS (NOVEMBER 1962)

A. (1) An invention reported under the reporting of new technology clause of this contract shall be presumed to have been made by a person described in paragraphs (1) or (2) of section 305(a) of the National Aeronautics and Space Act of 1958 (hereinafter called "the act"), and under the conditions therein described.

(2) With respect to these inventions designated as such by the contractor at the time of reporting, the presumption of (a) (1) above shall be conclusive unless the contractor at the time of reporting any such invention does one of the following:

(i) Submits to the contracting officer a written statement, containing supporting details, demonstrating that the invention had not been made under the circumstances set forth in either paragraph (1) or (2) of section 305(a) of the act; or

(ii) Notifies the contracting officer of the contractor's intention to file a petition for waiver of the rights of the United States to such invention, and files such petition within 3 months of such notification.

(3) With respect to other inventions, the presumption of (a) (1) above shall be conclusive if the contractor fails to take one of the actions set forth in (a) (2) above within 30 days after notification by the Administrator that the reportable item has been determined to constitute an invention.

B (1). If the contractor files a petition for waiver, he may nevertheless file the statement described in (a) (2) above. With or without a petition for waiver, the Administrator will review the information furnished by the contractor in such statement and any other available information relating to the circumstances surrounding the making of the invention and will notify the contractor of the decision as to whether the invention had been made under the circumstances set forth in either paragraphs (1) or (2) of section 305 (a) of the act.

(2) If the contractor notifies the contracting officer of his intention to petition for waiver as provided in (a) (2) above, but either (i) fails to file his petition within the time specified therein, or (ii) at the time of filing a petition for waiver, does not file an accompanying written statement in accordance with (a) (2) above, the presumption stated in (a) (1) above shall become conclusive.

c. With respect to each invention which becomes the exclusive property of the United States, contractor shall:

(i) Notify the contracting officer promptly following any public use or sale by the contractor of the invention or any publication by the contractor describing such invention; and

(ii) Furnish, upon written request by the contracting officer, such full and complete technical and other information available to the contractor as will be adequate for ready transposition to patent specification form and for effective prosecution of a patent application, and, in addition, shall execute or secure execution of documents and instruments as may be determined by the Administrator to be necessary for the preparation and prosecution of applications for letters patent covering each invention.

NOTE.—Patent Provisions of Contract No. NAS 8-11736 (NASA).

APPENDIX IV

A. Whenever any invention or discovery is made or conceived by the contractor or its employees in the course of or under this contract, which invention or discovery is inherently incapable of a use other than in the production or utilization of special nuclear material or atomic energy, the contractor shall promptly furnish the Commission with complete information thereon; and the Commission shall have the sole power to determine whether or not and where a patent application shall be filed, and to determine the disposition of the title to and rights in and to any invention or discovery and any patent application or patent that may result: *Provided, however,* That if the contract, when furnishing the complete information as to any invention or discovery advises the Commission that the contractor will file at its own expense, subject to security requirements and regulations, a U.S. patent application within 6 months of reporting, and designated foreign patent applications on such invention or discovery, subject to security requirements and regulations, the contractor shall retain:

(1) A nonexclusive, irrevocable, paid-up license for all purposes in any such U.S. patent application filed by the contractor and any U.S. patent issued thereon, and

(2) The title and rights in any such foreign patent applications or foreign patents secured by the contractor, subject to:

(i) A nonexclusive, irrevocable, paid-up license to the U.S. Government for U.S. governmental purposes and with the right of the U.S. Government to grant licenses to foreign governments for purposes of governmental use by such foreign governments pursuant to a treaty or agreement with the U.S. Government or any agency thereof.

(ii) Granting, upon request, nonexclusive royalty-free licenses to U.S. citizens, and to U.S. corporations when 75 percent or more of the voting interest is owned by U.S. citizens, for use in the production or utilization of special nuclear material or atomic energy; and agreeing to grant to foreign users and purchasers of the product of such a U.S. licensee a license, to use or sell such product to an assignee of the business or plant or as surplus, at a reasonable, nondiscriminatory royalty ordinarily to be at no greater royalty than contractor has charged its other foreign licensees.

(iii) The right of the contractor to grant such other licenses in accordance with applicable statutes and regulations.

(*a*) *Provided*, That if the contractor grants any licenses other than as provided in (ii) above, the same shall be for reasonable royalties or compensation, and

(*b*) *Provided further*, That if, after 3 years of the issuance of a particular foreign patent, contractor, its assignee or its licensees cannot demonstrate, upon Commission request, the practical application of the subject matter covered by such foreign patent, the contractor or its assignee shall, at the Commission's request, grant licenses on any such foreign patent to others at reasonable royalties.

(3) If the contractor does not desire to prosecute the U.S. patent application or any foreign application or maintain any foreign patent, the contractor, prior to abandonment shall afford the Commission an opportunity to take over prosecution of any such patent application or maintain any patent. The judgment of the Commission on these matters shall be accepted as final; and the contractor, for itself and for its employees, agrees that the inventor or inventors will execute all documents and do all things necessary or proper to carry out the judgment of the Commission.

B. Whenever any invention or discovery is made or conceived by the contractor or its employees in the course of or under this contract, which invention or discovery is inherently capable of a use other than in the production or utilization of special nuclear material or atomic energy, the contractor shall promptly furnish the Commission with complete information thereon; and the Commission shall have the sole power to determine whether or not and where a patent application shall be filed, and to determine the disposition of the title to and rights in and to any invention or discovery and any patent application or patent that may result:

Provided, however, That if the Commission determines not to file, the contractor may file any U.S. and foreign patent application subject to the Commission security requirements and regulations.

Provided, however, That the contractor in any event shall retain at least a sole (except as against the Government or its account), irrevocable, royalty-free license with the sole right to grant sublicenses, under said invention, discovery, patent application or plant, such license and sublicensing rights being limited to the manufacture, use and sale for purposes other than use in the production or utilization of special nuclear material or atomic energy. Subject to the license retained by the contractor, as provided in this paragraph, the judgment of the Commission on these matters shall be accepted as final; and the contractor, for itself and for its employees, agrees that the inventor or inventors will execute all documents and do all things necessary or proper to carry out the judgment of the Commission.

C. No claim for pecuniary award or compensation under the provisions of the Atomic Energy Act of 1954, as amended, shall be asserted by the contractor or its employees with respect to any invention or discovery made or conceived in the course of or under this contract.

D. Except as otherwise authorized in writing by the Commission, the contractor will obtain patent agreements to effectuate the purposes of paragraphs A, B, and C of this article from all persons who perform any part of the work under this contract, except such clerical and manual labor personnel as will not have access to technical data.

E. Except as otherwise authorized in writing by the Commission, the contract will insert in all subcontracts the Commission's standard type A patent provision.

F. It is recognized that during the course of the work under this contract, the contractor or its employees may from time to time desire to publish, within the limits of security requirements, information regarding scientific or technical developments made or conceived in the course of or under this contract. In order that public disclosure of such information will not adversely affect the patent interests of the Commission or the contractor, patent approval for release and publication shall be secured from the Commission prior to any such release or publication.

G. With respect to each invention or discovery in which the contractor is granted the principal or any exclusive rights under paragraph (b) of this article, the contractor agrees to provide written reports at reasonable intervals when requested by AEC as to:

(1) The commercial use that is being made or is intended to be made of such invention or discovery; and

(2) The steps taken by the contractor to bring the invention to a point of practical application or to make the invention or discovery available for licensing.

H. With respect to each invention or discovery in which the contractor is granted the principal or any exclusive rights under paragraph B of this article, the contractor agrees to and does hereby grant the Commission:

(1) The right to require the granting of nonexclusive, royalty-free licenses to applicants on any such invention or discovery unless the contractor, its transferees, or assignees demonstrate to the Commission, on request, that the contractor, its transferees, or assignees have taken effective steps within 3 years after a patent issues on such invention or discovery to bring the invention or discovery to a point of practical application, or have granted licenses thereon free or on reasonable terms, or can show cause why he, his transferees, or assignees should retain the principal or exclusive rights for a further period of time; and

(2) The right to grant licenses royalty-free or on reasonable terms to the extent that the invention or discovery is required for public use by governmental regulation, or as may be necessary to fulfill health needs, or for other public purposes stipulated in this contract.

I. In addition to the rights of the parties under the foregoing paragraphs in and to inventions or discoveries made or conceived in the course of or under this contract, the contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license in and to any and all inventions or discoveries of the contractor made, developed, or acquired prior to or on the effective date of expiration or completion of this contract, which are incorporated in any conceptual design or prototype furnished under this contract: (a) to make, use, and to have made and used the invention or discovery throughout the world, for U.S. Government purposes, for use in helicopter formation keeping systems, and (b) to sell and have sold any article, material, or product embodying said invention or discovery, and acquired or used under the foregoing license, as surplus or condemned public property as provided by law. Provided, however, that no license is granted herein as respects any item which, on the effective date of this contract, is a standard commercial item of the contractor. The acceptance or exercise by the Government of the aforesaid rights and license shall not prevent the Government at any time from contesting the enforceability, validity or scope of, or the title to, any rights or patents herein licensed.

All drawings, sketches, designs, design data, specifications, notebooks, technical and scientific data, and all photographs, negatives, reports, findings, recommendations, data and memorandums of every description relating thereto, as well as all copies of the foregoing, developed, prepared or furnished under this contract, shall be subject to inspection by the Commission at all reasonable times (for which inspection the proper facilities shall be afforded the Commission by the contractor and its subcontractors), shall be the property of the Government and may be used by the Government for any purpose whatsoever without any claim on the part of the contractor and its subcontractors and vendors for additional compensation and shall, subject to the right of the contractor to retain a copy of said material for its own use, be delivered to the Government, or otherwise disposed of by the contractor either as the contracting officer may from time to time direct during the progress of the work or in any event as the contracting officer shall direct upon completion or termination of this contract. The contractor's right of retention and use shall be subject to the security and patent provisions, if any, of this contract.

NOTE.—Patent provisions for contract No. AT (11–1)–1471 (AEC).

APPENDIX V

FEDERAL AVIATION AGENCY,
Washington, D.C., May 12, 1965.

INDUSTRIAL NUCLEONICS CORP.,
Columbus, Ohio

(Attention: Mr. Charles Badget.)

DEAR MR. BADGET: I wish to thank you for your consideration in forwarding a copy of your "Proposals for Digital Barometric Pressure Sensing Device Using Nucleonic Techniques" to our Agency.

A policy within the Agency does not permit us to review any material which is proprietary in nature. We respect the rights of the firms with whom we deal

and treat the proposals in an ethical manner. However, we find it necessary to return any proposals with a proprietary statement to the submitter without comment and without a review on our part. If you desire to delete the proprietary statement and to resubmit the proposal, we shall consider it along with other information that we have received on the subject.

Sincerely yours,

EDMUND BROMLEY, JR.,
Chief, Support Systems Branch,
Environmental Development Division,
Systems Research and Development Service.

INTERNATIONAL BUSINESS MACHINES CORP.,
Armonk, N.Y., June 2, 1965.

Hon. Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

MY DEAR SENATOR: I wish to offer my endorsement and support of the general principles contained in your bill S. 1809.

As you may recall, I endorsed the middle ground approach of your previous bill S. 1290 in my letter of May 7, 1963. In my opinion, your present bill represents a substantial improvement over S. 1290 in assuring the contractor of a royalty-free license and providing for a determination of invention rights at the time of contracting.

I suggest the following additional improvements for your consideration.

1. Where a contractor has filed a patent application or obtained a patent on an invention prior to entering into a contract, the Government's right should be limited to the normal nonexclusive license, even though the invention is first actually reduced to practice under the contract.

2. The Government should dedicate the inventions it acquires to the public rather than entering the business of licensing its patents on a royalty basis.

I hope these comments will be of assistance to you in resolving this complex problem and wish you utmost success in this bill.

Very truly yours,

J. W. BIRKENSTOCK, *Vice President.*

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
July 9, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Mr. Howard Forman, an industry witness, appeared before your subcommittee on July 7. In his testimony he quoted from a statement given in 1959 by a witness representing the American Patent Law Association before a subcommittee of the House Committee on Science and Astronautics, in which he submitted the names of five companies which purportedly had declined to accept contracts with NASA because of its patent policy.

In this connection, it may be useful to cite certain testimony in 1962 before the Monopoly Subcommittee of the Senate Small Business Committee by the General Counsel of the National Aeronautics and Space Administration. The following colloquy took place:

"Senator LONG. Do you know of any large concern which has refused to contract with you unless they get patent rights?

"Mr. JOHNSON. We submitted a list to another congressional committee of certain instances * * * *There have been a few such instances. In almost every case, by the time we were able to sit down and talk it out with them the contract was accepted.*"[1] (Emphasis added.)

In further hearings conducted by the same subcommittee in 1963 on the same subject, the following colloquy took place between the NASA Administrator and the subcommittee chairman:

[1] Hearings before the Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate, Mar. 27, 1962.

"Senator LONG. * * * Now, do you presently feel that you are not able to get a sufficient number of contractors available for research on your research and development contracts?

"Mr. WEBB. Generally, we have a large number of people who want to do work. The number of people qualified to do the highest quality of work is not large, but I think the patent waiver features of our law are not restricting us with respect to good contractors, although they are more restricted than other Government departments, as you know." [2]

I respectfully request that this letter be inserted at an appropriate place in the record so that a reader of Mr. Forman's testimony will be aware of this additional information.

Sincerely,

RUSSELL B. LONG,
Chairman, Monopoly Subcommittee.

BROWNE, SCHUYLER & BEVERIDGE,
ATTORNEYS AND COUNSELORS AT LAW,
Washington, D.C., August 31, 1965.

Mr. THOMAS C. BRENNAN,
Chief Counsel, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. BRENNAN: Concerning the testimony obtained during hearings on S. 1809, it may be of interest to point up a factor often overlooked in debates on what should be the legislative policy for apportionment of rights as between the Government and the inventor and/or developer of inventions important to the public welfare. This factor comes into play when legislation or executive policy seeks to assure by a general rule the public ownership for, and cancellation of, private rights where the Government has made a substantial or predominant contribution to the total development cost. In assuring such public ownership in cases where there are equities to favor that result it may often happen, in practice, that the private inventor or contributor has an equity which is wholly cut off unless care is taken to preserve his private right; and to respect the final clause of amendment V to the Constitution.

The U.S. Government experiences a very strong bargaining position in letting contracts to contractors dependent on such contracts for sizable portions of their business, and this position is not usually challenged. An important inequality arises where general regulations and administrative policies control individual cases rather than the equities of the case themselves. Nor is the private party always in a position of equality to test in court the application of administrative policy, since courts have a tendency to require proof that an administrator has exercised his authority in an arbitrary or capricious manner under a regulation before relief will be granted. Against these principles governing right to relief, supported by the sometimes overwhelming weight of legal talent available to the Government, the individual or small company finds it not worthwhile to challenge an administrative decision, if based plausibly on a general provision of law or a departmental regulation.

An example arises from closer review of the case reported by Mr. Walter A. Munns, President, Smith Kline & French Laboratories, in his statement to the committee on August 19, 1965. That case relates to cooperative work between a company and a research worker who was paid in part under a grant from the Department of Health, Education, and Welfare for investigations of steroids, for which $26,000 was expended each year for several years, but not directed at all to the subject of the cooperative work. Who first suggested that results of his study could be of possible use as a prescription drug to prevent incipient heart attack seems not to be clear. The suggestion that a particular steroid was worth further investigation for that purpose seems to have come wholly from the company. It appears further that no such use had been suggested or recognized as a result of his contract reports to the Government Department, and that if any suggestion was made, it was not seen to have value.

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[2] "Economic Aspects of Government Patent Policies," hearings before a subcommittee of the Select Committee on Small Business, U.S. Senate, Mar. 14, 1963, p. 317.

From this point the private company expended $250,000 to evaluate the drug for this new and urgent purpose, and proceeded to the point of proving its effect and safety in animal tests.

Now we have a contribution of a small sum, certainly not higher than the $26,000 allocated for general steroid research in one year, which could be regarded as the Government's contribution, and a private contribution some 10 times larger. Yet the company, despite its overwhelmingly larger contribution of $2 million required for producing an acceptable pharmaceutical product was denied any private right even though its contribution might then exceed 98 percent of the total cost of development.

It has long been urged by many that the doctrine of encouraging innovations and inventions should give way to the doctrine that he who pays for a development should own it. Yet the same doctrine of equitable ownership, when put into effect as between Government and its citizens as innovators, seeks to assert full ownership were private costs may be as much as 50 times greater than that of the Government. This is an example, perhaps extreme, but nevertheless real, of equities quite opposite to those often assumed to prevail generally.

Should not any general legislation carefully guard against the image of a Government which takes away from its citizens what they may contribute at private expense as well as protecting other public interests?

This letter is submitted on my own behalf for record purposes in the hope that ultimate legislation will not unfairly tip the balance in favor of big Government to the ultimate detriment of the people governed.

Sincerely,

WILSON R. MALTBY.

MINNESOTA MINING & MANUFACTURING CO.,
St. Paul, Minn., July 19, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: In the interest of clarifying proposed patent legislation before the Senate, the Minnesota Mining & Manufacturing Co. wishes to make a statement for the record, expressing itself with some amendments for Senate bill 1809. These amendments are prepared in an effort to provide more equitable treatment for contractors who carry out research and development contracts on behalf of the Government.

We wish to commend the Subcommittee on Patents, Trademarks, and Copyrights for the long extended hearings in the interest of developing sound governmental contract procedure. Of the bills presented at the hearing, Senate 1809, in our opinion, offers the best proposal for the establishment of uniform governmental contracts in the field of research and development. The committee has heard many times the various arguments regarding patent policies so we will devote our further efforts to the proposed amendments.

In the definitions, section 2, paragraph (c) should be revised to read:

"(c) The term 'contract' means any contractual arrangement set forth in writing, entered into between any Government agency and any other person where a purpose of the contract is the conduct of experimental, developmental, or research work, and the contract involves the expenditure of Government funds to reimburse the contractor for the conduct of the work. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract."

Section 2, paragraph (g) should be revised as follows:

"(g) The term 'made,' when used in relation to any invention, means the first actual reduction to practice of such invention in the course of or under the contract."

We think these changes should be made in the interest of clarifying the term "contracts" and in accordance with what appears to be the desire to reinforce contract provisions intended to insure that the U.S. Government receives all that it pays for in connection with Government research and development contracts. However, by the same token, we feel that this is a two-way street, and the Government should not get what it does not pay for. And at the same

time we might point out that the Government does not, in general, pay for the facilities (e.g., buildings and equipment) that the contractor has assembled, nor the expenses involved in obtaining and retaining the services of a highly skilled staff, nor the detriment to the contractor in losing the services of that highly skilled staff during the time that the contract is being performed on behalf of the Government.

Furthermore, in advocating revision of section 2(g) as indicated, we feel that inasmuch as the Government does not pay the contractor for ideas conceived prior to performance of the contract, by the same token the Government should not retain title to ideas merely conceived in the performance of the work. To guard against the possibility that the contractor will withhold or conceal useful or good ideas, and not disclose them to the Government, we propose to require at a later point in the bill that the contractor disclose to the Government all conceptions made during the performance of the contract work so that an evaluation of those can be made, and if the Government desires to go forward and reduce them to practice with Government funds, the contractor can be so notified; but in that event, the contractor shall have a royalty-free, nonexclusive license, with the right to sublicense others, should such conceptions be reduced to practice by the Government and later patented.

Section 3(b)(1) should be amended to read as follows:

"(1) Require the prompt and full disclosure by the contractor to that agency of any invention conceived or made in the course of or under the contract; and in the case of any invention conceived but not actually reduced to practice in the course of or under the contract, the contract shall provide that the Government shall, within 90 days after receipt of the information concerning such conception, inform the contractor of the Government's desire to actually reduce such invention to practice with Government funds;

Provided further, That in the event the Government fails to accomplish actual reduction of such invention to practice within 3 years after receipt of said report, or if the Government does not inform the contractor of its intention to actually reduce the invention to practice, and in either event, the contractor shall actually reduce such invention to practice using his own funds, then all right, title, and interest in and to such invention shall accrue to the benefit of the contractor; and both the Government and the contractor shall preserve information relating to such inventions in secrecy until the title thereto has been determined."

Section 4(a)(1) should be revised to read as follows:

"(1) The sole purpose of the contract is to create, develop, or improve products, processes, or methods which are intended for commercial use on a royalty-free basis by the general public; or required for public use by governmental regulations."

This revision is suggested in the belief that when the United States undertakes research and development work on products, processes, or methods which are intended for general public use commercially, this should be the stated and prime objective, so that prospective contractors will know if their business interests would be jeopardized by performing the contract work.

Section 4(b) in the portion on page 8 of the bill as introduced, line 5, after "position", should be changed to read:

"The agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after the invention has been identified, that there are in existence special circumstances, based on relevant evidence of record, which establish beyond a reasonable doubt that the public interest would suffer as the result of the contractor retaining the principal or exclusive rights in such invention."

The change is suggested on the basis that agency heads should not be put in the position of making a determination on the basis of speculation or the fear of criticism if their decision is to retain rights greater than a nonexclusive license on behalf of the Government.

Section 4(c) should be rewritten as follows:

"(c) As to any contract executed under this act, the determination of rights in any invention made by the contractor in the course of or under the contract shall be made by the agency head at the time of contracting."

It is believed that the postponement of determination of rights in patents can serve no useful purpose, and will only increase the cost to the public of Government research and development work. It may well be noted in this

connection that the United States may, at its election, acquire and use any invention for governmental purposes, regardless of patent rights and their ownership, at any time, and whether or not such patent is granted on an invention made in performance of a Government-sponsored contract (28 U.S.C. 1498).

Section 9, paragraph (c), should be revised to read as follows:

"(c) The number and general nature of such inventions with respect to which the agency has acquired greater rights than a royalty-free license in accordance with section 4, and a summary of the findings of fact upon which such determinations were made."

The change is suggested in order to provide the same type of review of actions of agency heads in connection with acquisition of rights greater than a nonexclusive license, as is required in the case of acquisition by the agency of rights no greater than a royalty-free license.

We thank you for the opportunity of expressing our opinion regarding proposed legislation.

Cordially yours,

WILLIAM H. ABBOTT,
General Counsel and Vice President, Legal Affairs.

NATIONAL SMALL BUSINESS ASSOCIATION,
Washington, D.C., July 20, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: In response to your invitation to submit additional material bearing on the issues involved in connection with the patent policy matters reflected in S. 789, S. 1047, S. 1809 and S. 1899, bills being considered by your committee, we are submitting the following additional comments and the enclosed studies, with the request that they be incorporated into the record of your proceedings.

REFUTATION OF SENATOR RUSSELL LONG'S ARGUMENTS

(*a*) Senator Long has made a great point that much of the Government's agencies and programs are already covered by existing legislation and "require title on behalf of the public." The fact that practically all of this legislation was accomplished through the use of the "rider" technique, whereby the legislation was passed without any significant discussion of the issues, without resort to committee hearings, and in most cases by voice vote without the presence of any substantial number of Senators, smacks of subterfuge in attempting to establish public policy without the knowledge, to say nothing of the concurrence, of a major portion of the Senate. On practically every occasion where the Senate has been permitted to cast a meaningful vote on the issue, the Long amendment has been defeated. What the legislation reported by this committee should seek to accomplish is to arrive at a fair, studied, and impartial determination of entitlement to commercial rights to Government-funded R. & D. inventions as well as the Government's entitlement to the fruits of privately developed inventions.

(*b*) Senator Long has attacked some aspects of international patent pooling which causes unfavorable international market conditions for American manufacturers. This is a variation of the attack on patents because of the antitrust implications of the limited monopoly conferred by patents. There is a simple answer to these "horrible examples"—enforcement of the antitrust and other laws which are intended to prevent these abuses. Cutting down private rights to patents, as we have previously stated to this committee, will at the most only inconvenience the larger firms, but for much creative small business will be a matter of life and death.

(*c*) In his defense of his position, Senator Long continuously muddies the water by equating consumer-oriented research such as that conducted by the Department of Agriculture and by HEW with defense and other nonconsumer-oriented research. The statement that "there is no risk in finding a market for the new product" is certainly true for new inventions completely developed for

the consumer market—but the exact opposite is true for most inventions with potential commercial application derived from defense, space or atomic energy research. The costs of developing a commercially suitable product from the bare R. & D. invention are almost invariably great. Senator Long is dead wrong when he says that the primary interest of contractors in obtaining commercial patent rights is to permit them to obtain "monopoly" profits. Classical "monopoly" pricing simply does not exist in the current marketplace, for a number of reasons well known to economists and most Congressmen. Of course, every businessman seeks to maximize his profits, but the primary reason for businessmen desiring to acquire patent rights is to insure that there is a reasonable prospect of recovering development costs and keep exclusive rights to manufacture the patented item to meet competition from substitute products. Without exclusive rights, the copier, who has not borne development and marketing costs, is in a position to undersell the developer—a grossly inequitable situation.

(*d*) One of the themes Senator Long keeps harping on is new industries which have grown rich on Government R. & D. starting from scratch in this field. I assume he means companies like Aerojet-General and TRW Co. (Thompson-Ramo-Wooldridge.) These are the examples of industries cited to which "billions of dollars of the taxpayers' rights have been given away." We do not believe that any significant inventions having commercial value have accrued to any of these corporations. They have grown rich on their research earnings. We call on Senator Long (as he is so fond of doing to those who do not concur with his point of view) to point to one instance of patent rights acquired by these corporations which have produced tremendous monopoly profits for these corporations. If cases exist where such valuable rights have been acquired we would also like to know how much private capital has had to be invested to market these inventions. (Parenthetically, no one in industry is seriously suggesting that these R. & D. based corporations really have any entitlement to R. & D. patents.) But even in the less extreme cases—the large corporations with many years of experience in a field of technology—we would be interested to hear of some of the horrible examples where the taxpayer's rights have been given away; where large corporations have acquired patents which were the basis for huge monopoly profits. We believe that since most advanced technology is interrelated, large companies with large patent portfolios as a matter of practical necessity must pool or cross-license patents, so that the only competitors likely to suffer are the small companies. Effective price competition between large firms who cross-license or pool patents is obvious in the everyday experience of everyone of us—the electrical appliance industries, automobiles, electronics, just to name a few. The conspicuous success stories in modern industry are those involving privately produced inventions mostly by small business which have prospered and grown—the Polaroid, Xerox, and Data-Control type of industries. We want to see more of these develop whether the patents are derived from private or Government funded research, and we want these patents made available to the small creative individual or business rather than in the hands of Government bureaucrats, even if it means that larger businesses will thereby also obtain the same rights. This course is in the public interest.

(*e*) Assuming without admitting that every argument made by Senator Long is logically correct, we believe that it is nevertheless in the public interest in most cases to give commercial rights to patentable R. & D. inventions to the contractor or inventor for the following economic reasons:

1. We know of no field in which a true classical monopoly can be obtained in the current consumer market; true monopoly pricing cannot be practiced in the present market for the following reasons:

a. There are always available substitutes which even if not as good as a desirable patented article, will restrict the seller in pricing—as the price of the patented article vis-a-vis substitutes gets out of line, the utility of the substitute increases in the mind of the consumer. A good example is the Polaroid camera and Polaroid film. Most photographers will agree that instantaneous processing of film has some highly desirable advantages; nevertheless, the utility of the product to the consumer is not so great that Polaroid products are disproportionately priced as compared with Kodak or other cameras and photographic supplies. This is the common situation in the marketplace. Monopolistic competition in consumer product lines is the rule rather than the exception. Patents are only one of a number of monopolistic elements which enter into distinguishing products and maintaining monopolistic competition—other factors are trademarks,

name brands, advertising claims, artistic (as opposed to functional) variation, packaging, geographic limitation of distribution and variations in quality. In many products where patents exist, patent claims or rights are the least distinguishing elements of competition, particularly if the market is dominated by a few large businesses.

b. The realities of large-scale production and consumer demand require that any product where the consumer exercises a choice between competing desirable expenditures must be rationally priced in regard to its utility. For example, we would probably all agree that a device capable of recording television programs for later reproduction, similar to the audio tape recorder, is very desirable and would command a large market. Assuming that a relatively inexpensive device were developed and were patented, what pricing policy would be adopted by the manufacturer? Obviously the price would have to bear some reasonable relation to the market. It would be a monopoly price but not in the classical sense. In the light of our knowledge of market demand and current pricing of television sets and audio tape recorders, we would conjecture that a video recorder would have to be priced under $500 to sell in quantity production, and to generate substantial profits. This is certainly not the classical monopoly price.

2. The proposed Federal Inventions Administration would certainly cost the taxpayer a great deal of money—probably much more than returns from commercially utilized inventions could ever hope to return in license fees and royalties. Costs to policing patent rights on the part of the Government involving court actions would be tremendous. Returns from nonexclusive licenses, even assuming a willingness to pay a fair royalty (not more than 1 percent of manufacturer's gross selling price) would be very low. If exclusive licenses are to be granted, disposal by public bid would be the only way to avoid favoritism and corruption in the administration. Most of the patents would probably still end up in the hands of the original developer with only nominal returns over costs of administration.

3. The tax aspects of patent exploitation by corporate developers are such that all profits would be subject to corporate taxes of 52 percent, plus taxation of dividends at individual rates. Much of the profit from private development in any event accrues to the Government in the form of taxes. Additionally the property rights in patents in many jurisdictions are also subject to property taxes.

4. In those few cases where an illegal monopoly is created the antitrust laws provide adequate remedies. Monopoly practices, including unfair pricing, may be reviewed by the FTC and the courts, and in extreme cases the courts can order licensing of patents or placing them in the public domain.

5. The labor implications of the course proposed by Senator Long are startling—to the extent that any policy restricts development of commercial applications, new employment opportunities are lost; but to the extent that U.S. patents are placed in the public domain foreign countries are free to copy (and even patent in their own countries) and using the fruits of U.S. skill and technology to produce and import the items into the United States to compete with our own sources of supply, and take away the jobs of American workingmen as well as the businesses which create them. U.S. patents give exclusive rights to the American manufacturer in the U.S. market and allows U.S. citizens to file for the foreign patents. Furthermore, under the McClellan bill, S. 1809, if a patented R. & D. invention is not practiced, the Government can force licensing or other disposal of the patent.

6. Commercial rights to patentable inventions developed by small business or individual inventors should accrue to them where they are to be used as capital for new business or to enhance existing small business.

7. Value of what is "given away" should be carefully appraised in the light of following considerations:

(*a*) In the commercial market the royalty value of a patent assigned or licensed to a manufacturer is usually in the neighborhood of 5 percent, seldom as much as 10 percent of gross sales, because it is generally recognized that marketing know-how and product development are the most important factors in selling a new product.

(*b*) The patent holder must guarantee the validity of the patent.

(*c*) The patent owner must agree not to compete or use his know-how for competing applications.

8. A prime purpose of certain proponents of the "title" theory may be to further weaken small- and medium-size creative industry, recognizing that the

strong middle class is the bulwark of our free enterprise system. The desirable alternative in the minds of these proponents is large industries controlled or owned by Government.

COMMENTS ON STATEMENT OF MR. JOHN M. MALLOY (DEPUTY ASSISTANT SECRETARY OF DEFENSE, PROCUREMENT)

We are shocked by the continued callous disregard of the Department of Defense of the real dilemma and hardships faced by the small business patent holder under existing law and procurement regulations, as shown by the comments of Mr. John M. Malloy on S. 1047. When we balance the simple inexpensive and effective procedure which would be set up under S. 1047 for permitting Government infringement of private patents where needed for national security, against the impossible situation now faced by small businessmen in trying to protect their patents and obtain fair compensation for their use, we are dismayed that any Government official who is aware of the realities of the two situations could reach the conclusions of Mr. Malloy.

Certainly none of us is trying to deny the Government the right to produce items urgently needed for national defense whether patented or not. S. 1047 would not in any way permit this result by injunction or otherwise. If the patented item cannot be fairly obtained from the patentee or a licensed source all that is required is a simple finding by the Secretary of Defense that national security requires infringement—this power could even be delegated to contracting officers if deemed desirable. What we seek to accomplish by supporting S. 1047 is to change current attitudes and philosophy which now practically require contracting officers to induce infringement of any and all patented items. We wish to see a reestablishment of a requirement where national security permits of purchasing patented items from licensed sources or, if they are unfairly priced, of purchasing acceptable substitutes. We also seek to reestablish a climate where procurement officials will fairly seek to obtain licenses for use of patented items and, where appropriate, pay fair royalties for such use. At present the legislation which permits acquisition of such rights might just as well be repealed for all the likelihood of any procurement officer now seeking to purchase patent rights. We must reiterate that for creative patent oriented small business reestablishment of a fair basis for dealing with the Government is mandatory if any substantial segment of such industry is to survive to serve the Government's needs.

Certainly, Mr. Malloy must have had tongue in cheek when he said, "removal of the power to secure an injunction against Government procurement does not deprive the patent owner of reasonable compensation for the unlicensed use of his patent. An action against the Government lies in the Court of Claims, and meritorious claims may be settled there. Under 10 United States Code S. 2386, the military departments are authorized to settle infringement claims administratively before the suit in the Court of Claims is brought."

We have pointed out and have numerous examples showing that for small business (the primary suffered) a suit in the Court of Claims is no remedy at all because of its cost and the delay involved. Furthermore, administrative settlement of claims cannot be made, under GAO rulings, in the common case where there is an indemnity provision in the infringer's contract and the infringer refuses to settle. All the cards are stacked against the small patentholder.

We further take issue with Mr. Malloy's statement—"The Department of Defense does not encourage unlicensed use of inventions as a matter of course * * *." This may be true as a matter of "top-drawer" policy, but the realities of the DOD procurement situation are that procurement officers not only consciously use every means overt or surreptitious to acquire proprietary designs, but to an extent aid, abet, and induce involuntary infringement on the part of suppliers.

We think that Mr. Malloy has confused the issue in regard to the real effect of S. 1047 by his studied harping on the injunctive remedy which lies in the background of this bill—the real purport of what has been said is that, from the standpoint of the DOD bureaucracy, it is much simpler to continue the passive state of affairs giving carte blanche to DOD officials and letting us small businessmen (who seem to be such a thorn in the side of DOD) continue to try to grapple with this impossible legal and administrative situation, rather than have his own people have to make the simple determination, in

appropriate cases, that national security requires infringement of a patent. If our defense administrators are incapable of reaching the simple judgment that a hat rack or a radar component do or do not involve national security, we better get a new team. The statement that making such determinations would delay Government procurement, in our view, is sheer nonsense and serves the same ends.

The end of achieving competitive pricing for patented items having no national security impact is also sheer nonsense in our estimation. No producer of non-essential items, patented or not, can impose "classical" monopoly prices on his product. Available reasonably priced substitutes tend to keep prices of all patented products at a reasonable level. Furthermore, the Government's broad know-how and coercive powers in the field of negotiated procurement are sound and sure means of keeping prices in line. We most earnestly ask the committee to examine closely the reasoning of DOD and to reject it by reporting some version of S. 1047; power to make determinations should be vested in the "head of the department or agency concerned" rather than in the Secretary of Defense to overcome the objectionable feature of having procurement actions of other departments or agencies reviewable by the Secretary of Defense.

COMMENTS ON STATEMENT OF J. EDWARD WELCH, DEPUTY GENERAL COUNSEL, GAO

The views expressed by Mr. Welch follow what is, in our view, a time-honored tendency on the part of the Comptroller General, in his excessive zeal to protect the public interest and interpret the will of Congress, to be pennywise and pound foolish. The real costs to the Government in terms of shoddy goods, costs of administration, legal expenses, and loss of indemnity rights which are part and parcel of patent infringing procurements are never included in GAO calculations. (But it is interesting to note that GAO was able to derive the startling proposition that by payment of ordinary business overhead in its procurements, the Government somehow is financing contractor's private research programs. Is the Comptroller General so naive that he fails to appreciate that all private research is ultimately charged off against goods sold, or does he believe that private research funds are provided by some genie or philanthropist?)

Mr. Welch blithely skips over the most important question of public policy which the Congress is being asked to validate or refute in the legislation which will be reported out by this committee—namely, shall we continue to support the private, free enterprise system through our patent laws, particularly as they encourage the establishment, proliferation, and success of the creative small business, or shall we retreat further into state socialism where everything either belongs to the Government or is effectively controlled by Government bureaucracy?

The very issuance of the Comptroller General's opinion of October 6, 1958, B–136916, interpreting the Defense Procurement Act in such a manner as to prohibit the then prevalent procedure of procuring patented articles by negotiation, served to repeal, for practical purposes, the authorization contained in 10 U.S.C. 2386 for the Government to purchase rights in patents. Again, as in the case of the Department of Defense witness, when Mr. Welch states that the patentholders rights are "preserved to a substantial if not complete extent by rights to reasonable compensation preserved in section 1498 of title 28 United States Code," he simply is not aware of the inadequacy and unfairness of the small businessman having to resort to this proceeding. We believe that a fair appraisal of total real costs to the Government would show that negotiated procurement of patented items from licensed sources would in the long run be cheaper and more equitable to all parties concerned. S. 1047 provides a mechanism to accomplish this purpose and still permit purposeful infringement by the Government where there is a national defense purpose for the procurement and supply from licensed sources is inadequate for any reason.

STUDY PREPARED FOR NSBA BY DR. BARKEV S. SANDERS

We have asked Dr. Barkev S. Sanders of the Patents, Trademarks, and Copyright Institute of George Washington University, Washington, D.C., to prepare for us a study of certain aspects of patent policy as they relate to small business. We asked Dr. Sanders to do this for us because we were aware of the tremendous background which he has acquired in this area in connection with previous statistical and analytic studies of the patent system.

The conclusion reached by Dr. Sanders in the enclosed study which were of particular interest to us, since they support and document some of our previous statements and recommendations to the Congress, are as follows:

(1) The value of patents to individual inventors and small business is very great.

(2) A very large proportion (50–60 percent) of patents developed through private effort and investment is actually used for commercial purposes.

(3) The allegation that there is widespread suppression of patents by corporations has not been verified by documented studies. On the contrary, it appears that unused patents are unused primarily because of economic considerations.

(4) Patents are more intensely exploited by small business than by large.

(5) Individual inventors and the small business sector continue to make a significant contribution to the advance of knowledge, invention, and patenting of inventions.

(6) The quality of patents applied for and issued, as attested by utilization, is increasing.

(7) Comparatively few patentable inventions result from Government R. & D. contracts.

(8) Inventions have little intrinsic commercial value in the hands of the Federal Government.

(9) The proportion of patents developed with Federal R. & D. funds put to commercial use is much smaller than for those developed with private funds.

(10) Companies engaged in federally financed R. & D. are usually not those with the highest skills in the area of development sought.

(11) The Government should waive all its commercial rights to patentable inventions because this would result in more commercial exploitation of economically worthwhile inventions.

We believe that the data provided by Dr. Sander's study will be valuable to the committee because it brings together much of the available statistical data regarding patent exploitation by business.

EXAMPLES OF GOVERNMENT INFRINGEMENT ACTIONS AGAINST SMALL BUSINESS

We are submitting as an attachment to this letter a compilation of complaints which have been assembled by our association, to present dramatically exact fact situations covering Government actions complained of by small business. I am asking the committee to delete the names of the complainants and other corporations referred to in the complaints, for a number of reasons—fear of reprisal, pendency of litigation, etc. We feel that these reported incidents which represent only a handful of the numerous complaints which we continue to receive should stir the committee to take appropriate action to incorporate some relief similar to S. 1047 in whatever legislation it reports to the Congress.[1]

In conclusion, we wish to express our appreciation for the opportunity to present these additional comments to the committee.

Very truly yours,

HENRY J. CAPPELLO,
Consultant on Patent Policy.

NEISLER LABORATORIES, INC.,
Decatur, Ill., August 25, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee of Patents, Trademarks, and Copyrights, Senate Judiciary Committee, Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: Reference is made to hearings held by your subcommittee on S. 789, S. 1809, S. 1899, and S. 2326.

Aware of hearings scheduled by your committee for August 17, I had requested an opportunity of presenting a statement at a later date inasmuch as it was physically impossible for me to be available on the 17th. In a letter of August 10, your chief clerk, Mr. Steven G. Haaser, graciously suggested that should I so desire it would be acceptable to submit a statement for inclusion in the record.

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[1] Material contained in committee files.

Toward this end, I have prepared a written statement which I would like to respectfully submit for consideration by your subcommittee for inclusion as part of the record pertaining to hearings on these bills. The statement is submitted in duplicate and I trust that it is in proper form for consideration by your subcommittee.

Respectfully yours,

C. J. CAVALLITO,
Director of Research.

STATEMENT OF DR. CHESTER J. CAVALLITO, DIRECTOR OF RESEARCH, NEISLER LABORATORIES, INC.

My name is Cheser J. Cavallito; I am currently director of research, Neisler Laboratories, Inc., Decatur, Ill. Until a few months ago, our company operated as an independent concern in the pharmaceutical industry. We are now a subsidiary of Union Carbide Corp. Throughout the period of almost 15 years that I have been with the company, we have been engaged in creating and marketing new drugs.

My personal qualifications are set forth in appendix A to this statement.

The above bills relate to the vitally important subject of rights to inventions made in connection with Government-financed research. I do not propose to discuss the provisions of the bills. Rather, I would like to present to you some of the facts relating to research in the field of new drugs, based on some 25 years of experience in this field. These facts, I beleive, show beyond question that the public interest is jeopardized by any legislation that would (1) impair the full and complete interchange of information and cooperation between academic and institutional scientists and industry research personnel or (2) remove the patent incentive in connection with the research and marketing of any new chemicals having possible drug utility. But before detailing these facts, let me discuss my general observations in more detail.

As I understand the situation, it is agreed by all concerned that the results of Government-financed research should be made available to the public to the maximum possible extent. The only question is how this can best be accomplished. Some have taken the position that where the Government pays for some part or all of the activity leading to an invention, there is some form of giveaway if the contractor (or, indeed, any private enterprise) is given ownership of the patent rights. One fallacy of this approach lies in the assumption that the contractor (or other private enterprise) acquires some sort of presently existing and commercially valuable right in a new product. At least in the drug industry this is not so. There may, indeed, be some patent rights or prospect of patent rights in a product that shows some promise of drug application and some indication that it might survive the long period of development and marketing before any return on investment is made. But there is almost never, if ever, a drug invention made during the course of Government-financed research that is carried to the point of commercial practicality at Government expense.

This is not due to any inadequacy of individuals engaged in Government-financed research. My experience—and I believe the experience of others who have observed the activity—is that the personnel involved do their best to give the Government full value for its money under the conditions they face. The missing ingredient is one that the Government never has supplied in the past and I do not believe can supply in the future. This is the spirit of enterprise. Unless there is a strong incentive to take risks nobody will do so. And without the risk taking, drugs cannot reach the point of practical application. Indeed, the risk taking required in the drug industry is probably greater than that of any other substantial industry.

Where Government patent ownership is not involved, our patent system is a vital factor in attracting risk effort inthe development of new drugs, and thereby improving our health. It also makes possible the publication of research findings and the interchange of scientific knowledge that vastly increases the rate of our scientific progress. The U.S. patent system is particularly strong. Without it, it is highly unlikely that the United States would have developed the world's strongest and most productive pharmaceutical industry. Of some 587 new single chemical drug entities that became marketed drugs between 1941 and 1963, 355 originated in the United States. U.S. firms accounted for 321 of these.

This record, I am sure, reflects the fact that a concern in the U.S. drug industry has a very strong incentive—through the patent system—to make the successive risk investments required to bring a drug to the point of practical application and usefulness to mankind.

To the extent the patent system does not apply as to a particular drug, this incentive is lost. Where the consequence of Government-financed research is a curtailment of available patent rights, the effect of the patent system as a stimulus to these risk investments is reduced, or even lost entirely. The spirit of enterprise is no longer fully effective as to such drugs. Their potential may never be realized because of lack of incentive to perfect and market them.

The patent system can be rendered ineffective as to a drug by Government-owned patent rights that are simply thrown open for use by anyone. It can also be rendered ineffective by premature publication disclsoure of the chemicals, which curtails available patent rights.

The history of drug developments supports a conclusion that it is necessary—as a practical matter—to have the strongest possible patent rights for new drugs. Any Government activity that curtails such rights may result in potentially important drugs remaining unexplored and never carried to the point of practical utilization for the benefit of mankind. The policy of the Government as to Government-financed research activity, may curtail possible patent rights by impinging upon the new drug development activities of a pharmaceutical concern at any one of many points in the long road from an idea to a perfected, marketed, drug. In essentially all practical cases, the extent of the Government investment in the particular product is small—especially in relation to the inventment required of the pharmaceutical company in further research and marketing of the drug. To show why this is so I devote the next portion of this statement to a general description of the steps required to carry a drug to the point of practical benefit to mankind, with emphasis on the risk decisions that must be made and on the occasions where Government-financed research activities may be involved.

The elements of risk, the decisions that must be made, and the particular capability of a business enterprise operating under incentives to make the decisions and thereby take the risks, is best brought out by tracing the history of a drug to the point at which it is available to the public. In so doing, I shall bring out both the work and contribution of the employed personnel of the business concern and the work and contribution of academic personnel who frequently play an important role in the overall sequence of events. Within the limits of this statement it is not possible to do more than state in general terms the various procedures and steps in making a drug available for practical use in medical practice. But the sequence set forth is present in nearly every case, including particularly the steps from idea to invention to commercial product. It should be added that it takes more than an idea to make an invention; it takes more than an invention to make a product; and it takes more than a product to make a drug commercially available where it can be used by mankind.

MAKING THE INVENTION

The first step in the long road to a new drug of use to mankind is the invention. For a new synthetic drug (that is, new chemical compound useful as a drug) the work begins with the idea or concept of the new chemical structure or structures, followed by devising a way of making them. For a new drug derived from a natural source, the work begins with the idea or concept that some natural plant or animal material may contain a material useful as a drug, followed by devising a way of testing, isolating, determining the structure and possibly synthesizing the active substance or substances. Under today's conditions, these steps are becoming increasingly more difficult and require much more vision and ingenuity than may appear—for the less difficult and more readily apparent drug leads have been pursued by others in the past.

In the case of a chemist in a pharmaceutical company laboratory, he is usually using his scientific knowledge and experience intuitively conceiving or visualizing new chemicals with a hoped-for, specific, biological property of potential value in medicine. Having so visualized the chemical (which may be a new synthetic chemical compound or some derivative of natural plant or animal material), he then proceeds to devise ways to make it.

In the case of an academic scientist, possible new drugs (whether new synthetic chemical compounds or derivatives of natural plant or animal materials)

are conceived predominantly in the interest of advancing scientific knowledge or a part of a teaching program. The academic scientist may or may not be interested in the potential biological properties of the substance. Many academic chemists, for example, are totally uninterested in such properties. An academic chemist in the chemistry department of a college of pharmacy, however, is usually interested in biological properties. In the case of an academic biologist, such properties are of major interest.

But whether the interest is only one of chemistry, or is also a matter of possible biological properties, the product envisioned must be made. In the case of some possible drugs, such as those in the sulfa-drug group, this may not present great difficulties. In the case of other drugs, such as some steroids and antibiotics, it may be exceedingly difficult to make the product. In many instances an academic scientist is at this point compelled to obtain the help of others. Frequently such help is obtained without cost from a pharmaceutical concern having experienced personnel and facilities for conducting unusual chemical processes.

After the product has been made, it is still necesary to demonstrate biological activity before there is a drug invention. This procedure is usually carried out quote differently in the laboratories of a pharmaceutical concern than in the case of a product originating in the work of an academic scientist. In the laboratory of a pharmaceutical company, the chemicals having potential drug activity are distributed to scientific specialists such as physiologists, pharmacologists, biochemists, endocrinologists, microbiologists, immunologists, or others having the skills and facilities to determine the presence of biological activity. These scientists conduct tests in the laboratory on experimental animals or living systems using test methods in which the performance of known drugs is recognized. They also look for any novel or unusual response that might suggest a new or unpredicted biological effect and possible application of the chemical. An important part of the work of these scientists is devising new testing procedures capable of detecting biological activities not previously subject to test or of improved responsiveness and reliability as to biological activities covered by previously available tests.

In the case of an academic scientist, biological testing is necessary to make a new drug invention just as in the case of the company scientist. However, in many instances an academic chemist is not interested, or only mildly interested, in biological properties. In such instance he will cooperate with a pharmaceutical concern interested in testing the products he has made, but will do nothing more to bring such testing about. Where the academic scientist is decidedly interested in biological properties, he may have facilities available to make such tests, in which event they are likely to be carried out. More frequently, however, he either has no facilities for this purpose or he needs more elaborate facilities than are available at the institution. In this instance the academic scientist must again turn to the laboratories of a pharmaceutical concern.

At this stage—making the invention—Government policy has a great influence on the extent products of possible biological activity are tested by pharmaceutical concerns. Usually the academic scientist who visualizes and makes the chemical compound (or other product) is working on some Government-financed research. This may be the very research that led to the making of the compound or other product. Under present provisions in many research contracts, the Government is believed to have full patent rights to such products, regardless of the contribution of a pharmaceutical concern in actually testing. This has forced pharmaceutical concerns in most instances to refuse to conduct such tests—for the only value of such tests to the concern is in leading to a drug which can be marketed under patent protection that will protect the necessary investment. It is essential, therefore, to have some way to provide reasonable patent rights to the pharmaceutical concern if the potential value of the products made by the academic scientists is to be realized in terms of drugs available for use.

It should be noted that in this instance there is no question of giving something away to a Government contractor who already receives compensation for services. The pharmaceutical concern receives no compensation from the Government in any event. In the past, the concerns have entered into patent agreements under which the concern obtains some exclusive rights sufficient to justify the initial biological testing and further drug development and marketing expense. If academic scientists (or their institutions) working under Government

contracts are permitted to retain sufficient rights to enable them to grant some exclusive rights to pharmaceutical concerns, this practice can continue. Otherwise, there is every indication that it will soon come to a complete halt.

I understand from discussions with lawyers that a pharmaceutical invention is regarded as "conceived" when the chemical is visualized and its probable activity identified. I also understand, however, that in some instances the "conception" is not complete until activity is demonstrated—but that under these circumstances the conception may not be that of the person making the biological tests, but rather may be considered to be that of the person who visualized the product and its probable activity that is later demonstrated to exist. Since an invention is regarded as "made" under a Government contract when "conceived" during the performance of the contract, it is my understanding that where an academic scientist visualizes and makes a product while under such contract, the invention is likely to be the property of the Government even if a pharmaceutical concern invests far more than the Government in biological tests and other activities.

If the biological testing of one or more products shows some promise of useful biological properties, it is necessary to undertake very substantial additional research before a product that may be even tested on humans is obtained. This activity entails some very important and risky decisions. The first decision is that of identifying the family of chemicals that should be made and tested to be sure that the chemical having the greatest desirable activity and the least undesirable activity is found. This is not a simple task. Endless variations in chemical structure are usually possible. A skilled scientist may be able to identify the structural components of the chemical that contribute to the activity and suggest the chemical variations that can most productively be explored. More typically, it is necessary for the chemist and the biological scientist to work in close liaison in preliminary tests directed to identification of the biological effects resulting from variation of parts of the molecule. In any case, an extremely difficult decision must be made in determining just what products should be prepared and subjected to biological tests.

This decisional process is part of the new drug development procedures that a pharmaceutical concern is designed to follow. It is particularly suitable for a business concern spurred on by the prospect of an important new drug that can be marketed under patent rights. If the testing of related products stops short of testing the optimum product, the resultant drug will not be the best possible. But if the testing goes beyond the point of diminishing returns, investment is needlessly increased and availability of the drug to the public is needlessly delayed. Decisions of this sort are best made in the environment of a competitive enterprise where wise decisionmaking results in profits and unwise decisionmaking may be economically fatal.

MAKING THE PRODUCT

The first step in making a product from the invention is to select the compound from among those tested which seems to justify further development. Among factors influencing a selection at this point are: chemical considerations—such as difficulty and cost of synthesis on a larger scale, stability, physical form of the chemical, specifications, etc.; biological considerations—such as spectrum of biological activities, absorption, anticipated difficulties from toxicity or metabolic disposition; pharmaceutical consideratons—such as formulation problems that might arise in converting the raw generic substance from the chemist's bottle to a stable, reproducible, functional pharmaceutical dosage form. It readily can be seen that the potential sources of difficulty are numerous and multidisciplinary. If a poor selection is made, this will be an expensive error in judgment because all of the work would need to be repeated if another compound later had to be chosen.

After a new chemical is tentatively selected for further evaluation, it is put through the paces of additional safety testing in animals and elucidation of a more complete biological profile. This, if a new compound were turned up as warranting interest because of its ability to lower blood pressure in animals, prior to its first evaluation in man it would be necessary to determine what other things the chemical might do in a wide variety of biological test systems and to conduct additional preliminary safety and toxicity tests. At this point, one is still a long way from knowing whether his new chemical is a drug.

If the acute animal tests show now limiting undesirable manifestations, subacute toxicity tests in animals are conducted for about 3 months. If the compound passes this safety test, then one can consider very careful, preliminary, "dose-range" explorations in a limited number of human volunteers.

The decision to conduct enough laboratory tests to prepare a compound for preliminary evaluation in man involves the assumption of considerable decision-making risk in commitment of resources. Furthermore, the decision as to how much animal work to conduct prior to preliminary evaluation in man is a weighty responsibility for the research and general pharmaceutical management.

Additionally, the Food and Drug Administration requires that an investigational new drug application be filed with them prior to the institution of any evaluation of an experimental drug in man. The basic responsibility and the risks inherent to this step nevertheless rest, as they should, squarely upon the pharmaceutical company or submitter of such a new drug.

The first and preliminary evaluation in man involves studies which often do not tell us whether the new chemical is active in influencing the disease for which it is of possible interest. Rather, the early investigations are designed to guide subsequent studies from the view of how much of the potential new drug substance can be safely administered to man without inducing limiting, undesirable side effects. These preliminary tests generally are referred to as human "dose-range" studies. These are conducted in human volunteers and by at least two independent, clinical investigator groups. If the new chemical shows undesirable features at this stage, it is dropped from further consideration. As one can see, an appreciable investment has already been made in coming to this point of no further pursuit. If, on the other hand, the compound does not show undesirable characteristicts, it yet remains to be demonstrated that it is effective for the disease condition to be treated. Many factors now enter into the design of steps beyond this point.

If a drug potentially will be used as therapy for a chronic disease, it will be administered for prolonged periods of time. In these instances one must begin even more extensive, expensive, and time-consuming, long-range animal toxicity studies to determine the safe dose range of the experimental drug prior to its administration for a significant period of time to humans with the disease. It is self-evident that a drug for treatment of an acute condition such as pneumonia, which would require administration of the drug for a limited period of time, poses a different kind of safety problem than one for treating diabetes, for example, which requires a day in and day out medication for the remainder of the patient's life. The decision to proceed to long-range toxicity studies involves significant calculated risk in the investment of resources. The decision to pursue clinical testing beyond the initial dose range studies commits the company to possible expenditure of very sizable sums of money over several years' time. The company expenditures for clinical studies involve not just internal costs, such as maintenance of a medical department, preparation of clinical supplies, etc., but financial support for external studies by clinical investigators. These external clinical costs include grant supports to the institutions where studies are to be conducted and reimbursements for the large numbers of often expensive clinical laboratory tests used to monitor the effects of the drug on the volunteer patient. Investigators of high caliber sought to conduct clinical studies of this kind also may be carrying on other research programs for which some financial support may have come grom philanthropic sources, or from local, State, or Federal agencies. Total isolation or segregation of every aspect of every projects by an investigator on the basis of source of funds is virtually impossible. It would cut off from the industry the services of many leading clinical investigators if the proprietary position in the company's drug were to be usurped by the Government whenever any part of the investigator's or institution's support of a drug study were associated with Federal funds.

Here the policy respecting Government-financed research by academic scientists again impinges on the development and marketing of new drugs. The pharmaceutical concern must be able to use the facilities of the academic clinical investigator. It cannot do so if the consequence of using these is to lose the patent rights that are essential to marketing of the proposed new drug. While I do not believe that—aside from exceptional cases—any present practice relating to Government-financed research contracts threatens the pharmaceutical

concern in this respect, any continuation of the recent trend toward ever-increased Government claim of rights may well do so. If this occurs the consequences will be disastrous to new drug development and marketing.

After collecting considerable amounts of data from animals and from human clinical work with a new experimental drug, one usually has an accumulation of encouraging and discouraging information which requires evaluation. There is no such thing as an ideal drug. No drug is without some shortcomings or limitations. Yet, if we are to be practical and make step-by-step advances in medical therapy, we must make realistic compromises with the ideal and in light of the best medical judgment determine whether the evaluated data from a new drug shows sufficient advantages to outweigh its limitations and justify its use in treatment of a disease. The company management once again must make a high-risk decision. Do the overall characteristics of the investigational drug merit its market introduction as a product? Errors in judgment escalate in costliness as a drug development program moves closer to the product stage. A new drug application filed with the Food and Drug Administration may require several years to clear. During this time, the company has considerable money spent which earns no income and in practice, usually continues to spend money on additional studies. Finally, that rare day may dawn for a pharmaceutical company on which it receives approval of its new drug application. To reach this point, an average of 5,000 compounds were prepared, studied, and discarded by the industry before the one became an acceptable, marketable product.

CONDUCTING A PHARMACEUTICAL BUSINESS

Having a new product is an exciting situation for any company. This is particularly true in the pharmaceutical industry. Having a product, however, does not guarantee that it will form the basis of a profitable business. The company may be compelled to make a major investment in a new factory installation to manufacture the drug substance. Pharmaceutical production facilities may need to be designed or added for manufacture of the product. Quality control, packaging, distribution, and marketing efforts are required. These costs are particularly high during the early periods of new product introduction. To these costs and problems one must add the ever-present possibility the drug just won't be a market success for any of several reasons. Furthermore, in a highly competitive industry, who knows how soon and from what direction a new product will appear which overnight will make yours obsolete?

STEPS IN THE DEVELOPMENT AND MARKETING OF A NEW DRUG FROM THE NORMAL LIMIT OF GOVERNMENT-FINANCED ACTIVITY IN MAKING COMPOUND WITH SOME ACTIVITY TO FIRST MONETARY RETURN

There are, of course, endless variations in the sequence of steps leading to a marketable new drug. General indications of what takes place may nevertheless be helpful to your committee in visualizing what occurs. I have accordingly attached hereto an outline of steps in the development and marketing of a new drug. The outline extends only from the point at which a chemical is found to have an interesting biological activity to the time of first sale of the drug that ultimately results. The total elapsed time could range from 4 to 8 years. The total investment could fall in the range of from about $2 to $12 million. These are not absolute limits, but do represent the ranges usually encountered today. All of this investment must be made on a further risk basis in the light of the chance that a competitor will market an equal, or better, drug during this developmental period or shortly thereafter. The pharmaceutical concern must have patent rights to justify this investment.

The Government investment in a potential new drug rarely extends beyond the point where it has been made by an academic scientist and some biological activity shown to exist (a demonstration that usually occurs in the laboratories of a pharmaceutical concern, to whom the compound has been given for this purpose). If the matter is dropped at this point, there is no drug suitable for marketing. If the matter is pursued, as illustrated in the outline, millions of dollars must be invested before there is any return. Such investment cannot be justified without patent rights. The initial Government investment in the making of the compound—perhaps only $10,000—is far outweighed by the investment of the pharmaceutical concern. It follows that Government policy

should be based on leaving to the contractor in such instance sufficient patent rights to enable it to grant rights to the pharmaceutical concern adequate to support investment necessary to bring the product to the point of utilization to the benefit of mankind.

One product having some pharmaceutical activity as tested in biological laboratory. (For every such compound, pharmaceutical concerns make and test many compounds. Where an academic scientist has made the compound, he may fortuitously hit upon one with some activity. If the academic scientist has been supported by the Government to any extent, the support does not normally extend beyond the point of having made such a compound.)

Synthesis of 25–100 related compounds for test and determination of optimum chemical; $50,000 to $200,000 invested by company.

Biological screening of 25–100 compounds; $15,000 to $50,000 invested by company.

Full biological laboratory profile of compound selected as optimum; $50,000 investment.

Preliminary, 3-month, animal toxicity tests; $10,000 investment.

Metabolism and biochemistry studies; $50,000 investment.

Pharmacy research and development; $50,000–$100,000 investment.

Human dose-range studies; $15,000 investment.

Long-term animal toxicity tests; $60,000 investment.

Pre-new-drug application human evaluation of drug; $25,000–$1 million investment.

Processing of new-drug application; $100,000 investment.

Introductory supplies, production facilities, marketing; $5 million investment.

First sale and monetary return

If drug is successful, and is not displaced too soon by an even better drug, the monetary return will be adequate to justify the investment made on the drug, together with investments made on unsuccessful drugs.

Total elapsed time from first compound with some activity to first monetary return: 4 to 8 years.

Total investment from first compound (and normal limit of any actual Government financed activity) to first monetary return: about $2 million to about $12 million.

APPENDIX A

STATEMENT OF QUALIFICATIONS, DR. CHESTER J. CAVALLITO

I received a bachelor of science degree in chemistry from Rutgers University in 1936. My doctor of philosophy degree was granted by Ohio State University in 1940. My field at this time was organic and physiological chemistry. In connection with work leading to the Ph. D. degree I also served as teaching assistant in the physiological chemistry and pharmacology laboratories in the medical school at Ohio State University.

Following receipt of my Ph. D. degree, I worked for 1.5 years at Goodyear Tire & Rubber Co. My work there dealt with the techniques for preserving food using synthetic polymer films such as Pliofilm as protective agents. After this I spent some 9 years at Sterling-Winthrop Research Institute, engaged in research work in the field of pharmaceuticals. Since January 1951 I have been director of research of Neisler Laboratories, Inc. (formerly Irwin, Neisler & Co.), of Decatur, Ill., which this year became a subsidiary of Union Carbide Corp.

I have served as secretary and as chairman of the Division of Medicinal Chemistry of the American Chemical Society and am a member of the editorial board of the Journal of Medicinal Chemistry. I have made presentations and have lectured in the filed of organic chemistry, drug mechanisms, and chemical pharmacology at meetings and at universities, both here and abroad. I have served as lecturer in the Department of Pharmacology at the University of Illinois College of Medicine. At present, I am serving on the Chemical Advisory Board for Walter Reed Army Institute of Research. I have authored approximately 70 scientific publications, and have received over 30 U.S. patents.

I am a member of Phi Beta Kappa and Sigma Xi honorary fraternities. In addition to the American Chemical Society, I am a member of the Chemical Society (London), the American Association for the Advancement of Science, the New York Academy of Science (fellow), and the American Society of Microbiology.

NEW JERSEY PATENT LAW ASSOCIATION,
Newark, N.J., May 28, 1965.

Re hearings June 1 and 2 on Government patent policy.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The New Jersey Patent Law Association has reviewed the provisions of S. 1809 and S. 1899 which are to be considered by your committee at the hearings to be held next week. Our association believes that your bill S. 1809, the Federal Inventions Act, is a very statesmanlike handling of this extremely important subject.

In the opinion of our association, S. 1809 is an excellent bill which provides full safeguards to the Government and the public while permitting a degree of flexibility to the Government agency head to administer the patent rights provisions in Government contracts to best serve the public interest.

We believe our national policy must be flexible because of the diverse types of Government research. In some cases where a field of research has been wholly Government funded and the contractor brings no private background to the contract work or where the research objective is to develop items for use by the public, for example, civil defense or public safety equipment, Government retention of title to Government-sponsored inventions may be desirable. In other cases where the research is primarily directed toward governmental activities but the Government wishes to encourage, but not support, future development in commercial areas, granting greater than nonexclusive rights to a contractor may be essential to encourage later private development.

We believe that to develop commercial uses at private expense of most inventions requires more than nonexclusive rights for the person who is to make the developments. Extremely large sums of money are required in most instances to develop a new product to its commercial stage. Only if a company can recover its development expenses and have some hope for a reasonable profit on the products which it sells, will it be willing to take the great risks involved in attempting to commercially develop a new product.

We believe that S. 1809 accomplishes the desired objectives of fully protecting the Government on inventions developed under Government contract yet at the same time, it gives a flexibility which will permit and in fact encourage, contractors to develop for commercial uses inventions which may have been made under or in connection with a Government contract.

We have two minor suggestions, however, which we should like to have considered in connection with S. 1809. Section 2(g) appearing on page 3 of your bill, defines when an invention has been made. We believe that the words "in the course of or under" the contract could be misinterpreted to imply that inventions made during work performed by a contractor not under the contract but which may be in a related field should be considered as coming within the definition when an invention is made. We believe that this could be clarified by changing the words "in the course of or under" to "in the performance of work called for or required under." Without this clarification, a contractor might be inclined not to accept Government contracts in fields in which he is already doing commercial work (which fields, of course, would be where he would have his greatest capabilities).

Our other suggestion regards section 4(a)(2) on page 7 of your bill. It refers to contracts for exploration into fields which directly concern the public health, welfare, or safety, and we believe it could be misinterpreted by contracting officials as applying to almost any contract which the Government might award. Almost anything which the Government gets involved in does in one way or another directly concern the public health, welfare, or safety. Therefore, we respectfully suggest that this section be expanded by setting forth those specific types of contracts which you would feel directly concern the three broad categories referred to in section 4(a)(2). Thus, for example in the field of public health, illustrative examples of such contracts would be those for developing means for curing and preventing diseases, matters related to sanitation and sanitary facilities, and improved food products for use by undernourished segments of our population.

In closing, our association wishes to thank you for your efforts in endeavoring to develop a national patent policy which will be fair and equitable both to the Government and Government contractors. Also, we wish to thank your committee for considering our statement on this matter.

Respectfully yours,

JULIUS J. DENZLER, *President.*

THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK,
New York, July 16, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: The Committee on Patents of the Association of the Bar of the City of New York, being charged to examine pending patent legislation and authorized to promote or oppose it on behalf of the association, has given consideration to the three bills now pending before your subcommittee on the subject of Government patent policy with respect to inventions under contracts relating to research and development, such bills being S. 789 (Saltonstall), S. 1809 (McClellan), and S. 1899 (Long).

As a result of such consideration, our committee has approved S. 1809 (McClellan) and urges the passage of this bill. The committee wishes to register on reservation, namely in feeling that the concluding sentence of section 4(a) should be clarified to avoid future interpretations of this provision (by Government agencies) which might, for all practical purposes, foreclose the application of such provision in the principal areas where exceptional circumstances may arise.

In general support of the bill, the committee recognizes that there are important reasons for enactment of a law prescribing Government patent policy in all fields of research and development contracts. The committee further recognizes that in support of S. 1809, there are very cogent reasons for permitting a division of rights, between the United States and the contractors, as to inventions arising under contract operations, and in particular for permitting the title or principal rights (saving always a license in the Government) to be acquired by the contractor in a number of appropriate circumstances, in contrast to proposals, as in one of the other pending bills identified above, that would essentially vest all rights in the Government, with relatively little exception even as to a license in the contractor.

Some of the reasons for favoring a balanced policy such as understood to be intended in S. 1809, including provisions allowing the contractor to acquire greater rights than a mere license with respect to the contemplated inventions under appropriate circumstances, are predicated on the concept that the incentive values of the patent system, relative both to the interest of the Government in getting maximum results of research and the interest of the public in getting the benefits of the inventions where possible, will be lost if major or all rights are inflexibly acquired by the Government in every case. Specifically, for example, and excluding situations where public interest in the nature or field of research conclusively demands retention of dominant rights by the Government as under subsections (1), (2), (3), and (4) of section 4(a) of S. 1809, it has been cogently suggested that in the absence of patent protection or substantial patent interest for the contractor.

(*a*) There will be minimal incentive to the contractor to identify and record patentable developments, so that the significance of such developments will be lost to the public.

(*b*) There will be little or no incentive for any one to commercialize products (in areas of general rather than Governmental use) since after the development of the products under the Government contract, no one would have any protection (against competition by others) in his investment for such commercialization.

(*c*) The small business contractor may find that the results of his research and development under the contract are free to be exploited by his larged competitor, to the detriment of the growth of small business.

(*d*) The contractor will be discouraged from making further developments with respect to subject matter which has in effect become dedicated to free availability to every one.

(*e*) Research and development contracts will be refused by many qualified contractors, especially those having the most valuable background of experience and ability, because of reluctance to risk their existing proprietary rights and to lose, in nongovernmental areas, the fruits of their long experience.

The position of the committee in support of S. 1809 accords with the position the committee has taken in past years relative to similar proposed legislation, i.e., relative to situations where demands of the national security or the general welfare warrant the Government's acquisition of greater rights in contract inventions and relative to the desirability of permitting a contractor to receive the greater rights in essentially all other cases. It may be noted, in passing, that as early as June 1961, the committee recorded its opposition to an earlier proposal for a Federal Inventions Administration, being of the opinion that such Administration would serve no useful purpose and that each Government agency can best administer its own patent affairs. It is noted that S. 1809 does not propose any such new Inventions Administration.

Turning to our reservation about the final provision of section 4(a) of S. 1809, i.e., the sentence now appearing in lines 18 to 22 of page 7 of the printed bill, it is strongly urged that some clarification is needed. Very apparently, the principal situation of "exceptional circumstances" would be one where the equities greatly favor the contractor, as when such contractor has an unusual amount of special knowledge and experience and a great deal of valuable know-how, either in research or commercial operation, in areas critically significant to the field in which the further research is desired. Under such circumstances, where the monetary consideration of the contract cannot possibly cover the very large value of the contractor's position, i.e., the value which will be of extraordinary advantage for the sake of the contracted research, it would seem plain that exceptional circumstances are present, including equitable considerations which predominantly favor the acquisition by the contractor of greater rights than a mere license. The public interest, in such case, may well be advanced by obtaining the services of this contractor (as most likely to be productive of desired results) through the inducement of the prospective acquisition of greater patent rights.

It is felt, however, that the present wording of this concluding provision of section 4(a) may well foreclose its applicability under these circumstances. Specifically, a Government agency might very likely adopt a theoretically warranted conclusion that the "public interest" is only "best served" by retaining title to all patents in the Government as the supposed representative of the public, there being nothing in the present language of the bill to indicate that strong equitable considerations in favor of the contractor might suffice to outweigh the presumably "best" position of the public in being granted full rights. Indeed, there is nothing in 4(a) that indicates any recognition of such equitable considerations, whereas the express recital of some limited situations involving such factors in section 4(b), could be construed as excluding any such considerations from the scope of the "exceptional circumstances" provision in 4(a). It is noted, in that connection, that this last provision is the only exception to the other parts of section 4(a); the benefits of section 4(b) are apparently not applicable to any situation coming within the numbered subsections of section 4(a).

We believe that the danger of this restrictive interpretation of the final proviso in section 4(a) is very real, and that it will result in serious disadvantage to the Government; i.e., inability to obtain the services of the best qualified and most productive contractors for research, especially in areas contemplated by section 4(a) (1) and (2), since those contractors will feel little inducement to sacrifice their hard-earned knowledge and experience.

By way of positive recommendation, it is suggested that the final sentence of section 4(a) (p. 7, lines 18 to 22 of the printed bill) be amended to read as follows (the amendment being by insertion of the wording marked for emphasis):

In exceptional circumstances, *which may include any equitable considerations that predominantly favor the contractor*, the contractor may acquire at the time of contracting or upon disclosure of the invention, greater rights than the nonexclusive license specified in section 3(b) (3) if the agency head certifies that such action will *advance or* best serve the public interest.

It is believed that amendment along these lines is desirable and necessary to clarify what we assume is the basic intent of the proviso; namely, to permit an exception where equitable considerations strongly favor the contractor. With the added wording, it will be plain that equitable considerations are to be taken into account, here as well as in the limited area of section 4(b). At the same time, the contracting agency can feel authorized to grant the exception if such action will truly advance the public interest; for example, as under the circumstances explained above, while there will be no compulsion on the agency to adopt a theoretical interpretation that the retention of essentially full title to patents is practically the only action that can be defined as "best" serving the public interest.

In conclusion, our committee appreciates this opportunity of expressing its support of the bill, on behalf of the Association of the Bar of the City of New York, and at the same time strongly recommends clarification of the above-noted provisions in section 4(a); e.g., as by amendment along the suggested lines, for the sake of basic workability of the general Government patent program, and, indeed, for the real interest of the public in getting the highest productivity and best results for its research dollars.

Respectfully submitted.

ROBERT S. DUNHAM,
Chairman, Committee on Patents.

THE NEW YORK PATENT LAW ASSOCIATION,
New York, N.Y., July 6, 1965.

Re bills to establish a national patent policy.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: This letter is submitted in lieu of an appearance and testimony on behalf of the New York Patent Law Association. Our association is very active and includes in its membership a majority of the lawyers in New York City, western Connecticut, and northern New Jersey who specialize in patent and trademark matters. A committee of our association has, for a number of years, been assigned the sole task of reviewing proposed legislation and other writings relating to Government patent policy and guiding our association's position with respect to this matter.

We first want to thank this subcommittee for holding hearings and accepting statements on the pending bills on Government patent policy. Our association strongly endorses the statement, made at the time S. 1809 was introduced, that: "it is clearly the intent of Congress that the basic guidelines of Government patent policy should be determined by the Congress" and "that the preferred method of accomplishing this objective is by the enactment of a comprehensive bill rather than by individual amendment to every bill authorizing Government research programs."

We have studied the bills now before this subcommittee designed to establish a uniform national policy concerning property rights in inventions made through the expenditure of public funds. We favor the passage of S. 1809 and recommend that it be enacted as soon as possible for the following reasons:

1. S. 1809 proposes a policy which recognizes the contributions of each of the parties.

2. S. 1809 offers the best opportunity for the development of an effective and equitable Government patent policy.

3. S. 1809 will prevent further deterioration of the patent system by piecemeal amendments to legislation authorizing research and development.

4. S. 1809 will provide a basis for incentives necessary to assure that technical advances resulting from Federal programs are utilized in non-Government areas with consequent benefits to the public at large.

We oppose enactment of S. 1899 because it provides for an inflexible Government title-to-all-inventions policy; it fails to recognize the equities of the contractors; and it can only serve to stifle the incentive of the contractors on which the Government must depend. We accordingly urge this subcommittee to report legislation which will provide the flexibility necessary to varying Government missions and the objectives sought by their research. Such legislation must, at

the same time, recognize the equities of contractors and recipients of Federal grants.

We are prepared to expand our statements in support of our endorsement of S. 1809 and our opposition to S. 1899. We have not submitted a more detailed review at this time because we have followed the statements submitted to date in support of S. 1809 and believe they set forth adequate and compelling reasons for the passage of S. 1809 rather than the inflexible and one-sided S. 1899.

We have drafted a limited number of minor amendments to S. 1809 which we believe would clarify the language, strengthen the position of our Government and our industries vis-a-vis foreign governments and industries, and increase the prospect of utilization of the inventions in nongovernmental fields.

Rather than extend this letter unduly, we will be pleased to present these suggested amendments at the request of the chairman or any member of this subcommittee to each of whom I am sending a copy of this letter.

Respectfully submitted.

JOHN N. COOPER, *President.*

NORTH AMERICAN AVIATION, INC.,
El Segundo, Calif., May 28, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, U.S. Senate, Washington, D.C.

MY DEAR SENATOR MCCLELLAN: We wish to submit the present statement in connection with the hearings presently being conducted by the Subcommittee on Patents, Trademarks, and Copyrights on proposed legislation concerning the disposition of inventions arising under Government contracts. The committee is to be commended for its thorough study of the complex patent rights problem, for the many hearings, studies, and reviews it has made over the past few years which have culminated in S. 1809 in the present Congress.

We are particularly pleased that the committee is attempting to formulate a uniform and equitable policy for all Government agencies, flexible in practice, which recognizes the need to stimulate the development and utilization of inventions by industry while recognizing and protecting the paramount public interest in technological growth. We recognize that the present diversity of legislation and policies reflects the different histories and statutory obligations of the various Government agencies but the resulting thicket now causes confusion, delays, and uncertainties to the Government, and to its contractors and vendors at all tiers. At present a contractor is faced with different patent requirements depending upon which agency he is dealing with even though the subject matter may be the same. The need for comprehensive legislation and the avoidance of further fragmentation is therefore apparent and urgent.

In developing advanced new defense and space systems of high technological content for the Government our company relies principally upon our strong technical capability in meeting specific contractual obligations and to generate the knowledge required to undertake new assignments. While our ability to acquire the skills to continue to meet increasingly complex technical problems in many disciplines is our principal asset in competing in the Government market, we nonetheless feel that patent factors can play an important role in bringing the results of work of companies like ours to other fields. Moreover, as a large prime contractor, our own performance is dependent upon that of a great number of subcontractors and vendors. It is the experience of DOD and NASA, as well as our own, that a patent policy which causes a vendor or subcontractor to fear loss of his proprietary position is a severe impediment to efficient administration and performance of program responsibilities. The protection of the proprietary position and commercial status of such smaller contractors is required not only for reasons of fairness, but also for efficient procurement. For these reasons we have a continuing interest in legislation on this subject.

We should like to express our strong support of the principles embodied in S. 1809. We believe they represent a sound balancing of the interrelated national interests which must be considered in establishing the patent policies of the United States. We are suggesting, however, certain ways in which we believe particular provisions of the bill could be clarified and strengthened.

The attached memorandum prepared by my staff discusses these suggestions and amplifies the considerations which we think should be reflected in an effective statute.

We wish to assure you of our continued willingness to cooperate in this important effort of the committee.

Sincerely yours,

J. L. ATWOOD, *President.*

MEMORANDUM

This memorandum amplifies the comments contained in the accompanying letter.

An important problem in the disposition of patent rights under Government contracts is to provide an effective means of transferring the inventions from the Government area to the often entirely different civilian environment. The task is to provide the necessary incentives to inventors and corporations to bring new products into the stream of commerce and benefit the people, while preventing unnecessary restrictions. Unless this is done the public will not obtain the full return from the current vast Government expenditures in R. & D. The experience over a number of years has been that such translation is frequently difficult, expensive, and unsure. Products of extreme technical complexity and sophistication developed for specific mission requirements often have no other use, and indeed their development is initially undertaken because of the absence of their commercial availability.

The utilization of developments originating under Government contracts thus poses more difficult problems than have been generally appreciated. It is considered that such utilization can be best accomplished with the traditional incentives offered by the patent system in the framework of our private ownership system. However, where a contractor is unable or unwilling to bring a patented product to the commercial market after a reasonable time it is just that the rights be then made available to others since the premise upon which the rights were granted has not been fulfilled and the public has not received full benefit.

There are still other areas where the most effective utilization of technical developments arising from Government programs can be best made by industry. It is understood to be national policy to foster the exportation of defense information to friendly countries in the interests of our national defense and foreign policy objectives, and also to obtain a return on defense investments from foreign countries. Some agreements in this area call for continuing cooperation between companies involving technical assistance, consultation, training of personnel, and exchange of technical data. Such programs involving the transfer and utilization of highly sophisticated technology can only be effectively conducted in the context of a private association of companies. While in many of these agreements involving the broad exchange of complex military technologies, the technical data and its knowledgeable utilization are of principal importance, patents are often valuable elements in the negotiation of a successful relationship. In other cases, which involve licenses of lesser scope directed to specific products whose design could be readily copied, foreign patents assume greater importance as the essential element of the agreement. All such activities are in furtherance of our national objectives, and their continuance should be uniformly sanctioned and encouraged under any new patent legislation.

Our study of S. 1809 indicates that most of the policy considerations discussed above and in Mr. Atwood's letter have been met. By permitting the Government contractor to retain patent rights in large areas, particularly those looking to the commercial markets, the results of Government research activity will be made available more readily to the entire economy through incorporation in commercial products. At the same time the bill recognizes and protects the predominant public interest in new technology, in providing means for insuring that the technology is in fact applied for public purposes, and to prevent the imposition of unreasonable restrictions on the use of technology. In areas of particular public concern or exclusive public sponsorship of technology, patent rights may be retained by the Government. Where the contractor retains patent rights, the contractor may be required to grant licenses to others when he has not in fact placed the invention in the stream of commerce.

Our suggestions for clarifying and improving the bill include the following: in section 4(a), provision for greater use of advanced waiver power, guidance on the application of the criteria, and administrative and judicial review of agency determinations applying this section; in section 4(b), modification of the requirement that a contractor must have an established nongovernmental commercial position in order to retain principal rights; and section 8, provision for the royalty-free licensing to all U.S. nationals of those patents in which the United States will retain title under this bill.

Section 4(a) delineates four criteria under which the United States shall acquire the principal rights in any invention made under a contract. These criteria are broadly stated and in order to insure their application in a uniform manner guidance should be given as to their application. In particular, the categories now require the disposition of rights at the time of contracting based upon the purpose and the technology of the contract. The nature of inventions actually made under the contract is not a factor. However, such inventions may relate only incidentally to the broad purpose or technology of the contract. For example, in an advanced space program, inventions are frequently made on such things as valves, fasteners, and welding techniques in which a contractor has an existing patent or industrial position. Therefore, provision should be made so that the Government would not be required to acquire exclusive rights in those inventions which are not of a dominant public interest under section 4(a) criteria.

In addition, liberalization of the provisions in section 4(a) to provide for advance waiver of Government rights in inventions at the time of contracting is recommended. This would considerably ease negotiation and administration of Government contracts. In subcontracting, for example, we find that a subcontractor wishes to establish his rights at the time of contracting to avoid uncertainties and time-consuming procedures for obtaining waivers on each invention. The prompt filing of patent applications would also be encouraged, and under this proposal the Government would suffer no loss, since the various safeguards of the bill would still be retained.

While review of agency determinations is desirably provided for in most cases, review is apparently not contemplated for agency action under section 4(a). This apparent absence is unnecessarily severe, would deny the customary review of procurement agency officers' decisions, and would not promote uniform practices. Finally, section 4(a) is more restrictive than the corresponding one in S. 1290, and while it is similar to a section in the President's memorandum of October 10, 1963, it does not have the flexibility of that section. Section 1(a) of the President's memorandum, after listing the categories where the Government would normally acquire exclusive rights (virtually identical with subparagraphs 1–4 of sec. 4(a)), goes on to provide that greater rights may be acquired by the contractor after the invention has been identified, where the invention is not a primary object of the contract, and the acquisition of greater rights is a necessary incentive to further investment and development.

Section 4(b) provides that in contracts calling for work in a field of technology in which the contractor has an existing technical position and competence he may ordinarily retain exclusive rights. However, a requirement for testing the contractor's technical competence in such field is that he have "an established nongovernmental commercial position." There are strong policy considerations for modifying this requirement by referring instead to a contractor's industrial or patent position. The principal consideration is that it would help the growth of new and often small companies and also the diversification of those companies which are now largely reliant on Government contracts. It would also foster the wider distribution and utilization of Government-developed technology.

A further suggested revision is directed to the utilization of patents acquired by the United States. The text of section 8(b) would sanction the licensing of patents for royalties by the United States and section 8(a) the bringing of suits for patent infringement against citizens of the United States by the Attorney General. It is believed that such activity by the Government would be ineffective in practice and would be the source of unnecessary controversies and litigation. It would clearly be inequitable to deprive the inventor-contractor of an invention on the basis that it falls within one of the categories of section 4(a) and that he has insufficient equities to retain an interest therein, and then grant the rights to another person with even less equity.

Moreover, the agency in granting exclusive licenses in Government-owned patents would be undertaking to direct the course of private technology and predict the course of competitive trends. Few of the agencies have had the requisite experience necessary to analyze the course of future development in civilian areas of technology and in general are not equipped to make determinations where competitive market forces are primary factors. If the contractor keeps title and is required to license others upon his own failure to exploit the invention, as is provided for in the bill, the public is spared the cost of paying for the Government administration of a licensing program, and further the contractor, who is most likely to exploit the invention, will be given the first opportunity to do so. It is recommended, therefore, that all inventions owned by the United States should be freely available to all U.S. citizens and corporations.

While the foregoing are the principal revisions suggested, there are other changes of a more technical nature which will not be specifically commented upon. If the committee wishes we would be pleased to furnish the text of language which would accomplish the changes suggested above as well as other more detailed changes.

THE UNIVERSITY OF TENNESSEE,
DEPARTMENT OF PHARMACOLOGY,
Memphis, Tenn., August 30, 1965.

HON. JOHN D. MCCLELLAN,
Committee on Patents,
U.S. Senate,
Washington, D.C.

DEAR SENATOR MCCLELLAN: First permit me to express my appreciation for initiating arrangements whereby my request to appear before the committee might be honored. I do wish to take this opportunity to express my regret that it was necessary for me to withdraw my request to appear on Tuesday, August 17. However, the pharmacology meetings in Philadelphia required me to be there on that day. Therefore, I will attempt to present to you in writing my views pertaining to bill S. 1809, which currently is being considered.

This bill, I am certain, represents a great deal of thought and effort and I consider it to be far superior to others such as 1899, submitted by Senator Russel Long.

First, possibly, I should introduce myself. I am professor and chairman of the Department of Pharmacology at the University of Tennessee Medical Units, Memphis, Tenn., a position which I have held since 1947. Previously, I held a similar chair at the University of Georgia College of Medicine, Augusta, Ga. I am a member of a number of scientific societies, including the American Society for Pharmacology & Experimental Therapeutics, American Society of Physiologists, American Heart Association, Sigma Xi, and Schwizerischen Vereins der Physiologen and Pharmakologen. I have conducted an active program in research in many fields and have published widely in several fields. I have no direct connections or positions with any pharmaceutical firm. At times, I have served as consultant for NIH and U.S. Food and Drug Administration.

As a citizen, I recognize that definite clarification is proper and necessary to protect the Federal Government and to establish reasonable policy and laws which will permit and encourage industry, the Government and the scientists to work together to develop knowledge which will provide all of us with better health and better medicine.

As I read the bill, I was disturbed by sections 3 and 4. Section 4(a)(2) states that the exclusive rights shall be acquired by the agency head in behalf of the United States at the time of entering into the contract when (p. 7, line 4) "the purpose of the contract is for exploration into fields which directly concern the public health, welfare, or safety." Practically all work dealing in the area of medical sciences could be considered directly concerned with the public health, welfare, or safety. This means that the agency head, in order to protect himself, must acquire at the time of entering into a contract, principal or exclusive rights to the inventions made by the contractor. True, this broad interpretation may not be given to section 4(a)(2) and, yet, agency heads in the Government must be conservative concerning such decisions. My experience has been that agency heads protect themselves and they can be expected

to acquire these exclusive rights very widely, if not in all cases involving areas of research related to medicine.

My experience and participation in research extends over a period of approximately 40 years. In the early days, my support was entirely from the university and from industry. As the economy of the Nation grew, and possibly as my contributions increased, I received appreciable governmental as well as industrial support.

Any bill which is passed by the Congress should not interfere or prevent scientists from getting support from many sources. It would be a most serious mistake to force the scientists of this country to depend entirely on the Government or entirely on industry and research foundations for their support. As scientists, we need the access to the new drugs and new chemicals which industry manufacturers, since they are frequently our tools whereby we learn more about disease processes. As I read this bill and think back over my experiences, it appears to me that this bill will tend to force many scientists to either accept Government money, or industrial money, but not both. Inventions are frequently the result of slowly developing ideas which mature into definite inventions. It is often impossible to be certain of the portion of the invention conceived while working under an agency or while working under contract on a project financed by a pharmaceutical firm, or while working on university supported programs. The most profitable and worthwhile research is frequently accomplished when the scientist and his associates are investigating a disease process with Government and industrial laboratory support and when they are using tools in the form of drugs or new chemicals to determine their effect on this disease process. These new chemicals are often the key to providing new information on the pathology and physiology of the disease. Under the regulations, as presented in bill S. 1809, it seems to me that scientists will be forced into the awkward situation where they will have accepted, in a sincere manner, financial support from the Government and from an industrial firm, and then find themselves confronted with a situation that they have made a discovery in performing studies supported by the Government, industry, and the university. It is more or less like whether breakfast, lunch, or dinner was the meal which made a boy grow into a man. It is my feeling that the university has definite rights and responsibilities and these should not be denied to them by a blanket clause requiring all discoveries to become exclusive property of the Government. Many universities have benefited from a wise policy pertaining to discoveries—the Wisconsin foundation is an excellent example.

It is my sincere hope that the bill can be so formulated that it will not remove the stimulus of granting financial rewards to productive efforts and will not interefer with cooperative programs involving support from funds from several sources. I know that you recognize the contributions that American industry and private enterprise have made to the improvement of medicine under the system which has been operating. The private enterprise system must be preserved while we are protecting the Government investment. I feel that the bill, as written, will hamper the development of new drugs unless a means is found to provide more freedom for the scientist to utilize new chemicals and new drugs, as well as receive financial support from the Government.

Most sincerely yours,

ROBERT A. WOODBURY, M.D., Ph. D.,
Professor and Chairman.

PATENTS, TRADE-MARK, & COPYRIGHT SECTION,
STATE BAR OF TEXAS,
July 6, 1965.

Senator JOHN L. MCCLELLAN,
U.S. Senate,
Washington, D.C.

SIR: In my capacity as chairman of the Patent, Trade-mark, & Copyright Section of the State Bar of Texas, I am herewith transmitting to you for consideration by you and your Subcommittee on Patents, Trademarks, & Copyrights of the Committee on the Judiciary six copies of two resolutions passed by the Patent, Trade-mark, & Copyright Section of the State Bar of Texas at its last annual meeting on July 2, 1965. One of these resolutions sets forth the views

of the section relative to bill S. 1899 introduced into the 89th Congress by Senator Long and the other resolution sets forth the views of the section relative to bill S. 789 introduced by Senator Saltonstall and bill S. 1809 introduced by you.

The section hopes that your subcommittee, and ultimately the Congress, will adopt the views expressed in these resolutions.

Very truly yours,

MELVIN F. FINCKE, *Chairman.*

RESOLUTION

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas believes that progress, advancement, and the public good are best served by private enterprise rather than by Government intervention or ownership; and

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas believes that the patent system has demonstrated over the past many decades that it affords a vital and effective incentive to private enterprise to assume the economic risks involved in developing new products, in introducing them to the public, and then promoting their use; and

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas is convinced that the Government cannot and should not assume a monopolistic postion with respect to the exclusive rights afforded by the patent grant and cannot and should not undertake the introduction and exploitation of new products in the public marketplace in competition with private enterprise: and

Whereas bill S. 1899 has been introduced into the Senate of the United States and has the purpose of (*a*) requiring the United States to take exclusive rights and title to any invention made in the course of or in consequence of any scientific or technological research development or exploration activity and resulting directing or indirectly from any contract or lease entered into or any grant made by, or on behalf of, any governmental department agency; and (*b*) establishing in the executive branch of the Government a Federal Inventions Administration: Now, therefore, be it

Resolved, That, the Patent, Trademark, and Copyright Section of the State Bar of Texas (*a*) opposes the extreme and inequitable approach of bill S. 1899 introduced into the 89th Congress toward inventions resulting from Government contracts; and (*b*) opposes the establishment of a Federal Inventions Administration as needless, costly, and against the best interests of this country and the principles upon which it was founded.

HOPE COLLEGE,
Holland, Mich., July 27, 1965.

Hon. JOHN MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: In your concern with the bills S. 789 (Saltonstall), S. 1899 (Long), and S. 1809 (McClellan), I think your bill, S. 1809, is so far the best compromise between Government and private industry and the extent of control each should have on patent rights. American industry, with its inventiveness, research, and production, has found competition not only the spark for new ideas but a necessary weapon for fighting the evil of profiteering. Bill S. 1899 seems to restrict research and industry in a way by placing patent rights in the hands of the Government whenever any Government money is used in any way in the research or production of a thing.

This seems an unnecessary kind of restriction since all private property is subject to the right of eminent domain in the Government, and may be taken, in payment of fair compensation, whenever a genuine public need is demonstrated.

Scientific industry and technology must make profits to help guarantee further research and to pay the often high cost of manufacturing. It is a moot question whether the public is more greatly benefited financially by paying the margin of profit over the counter or by paying possibly larger amounts through taxes. Federal research expenditure for 1958 was over $2½ billion. It would be interesting to know comparatively the number of new discoveries from research resulting from Government-sponsored research as contrasted with that of private research. Private pharmaceutical industry, for instance, has developed and discovered most

of our new lifesaving drugs. We must protect this kind of research to the best of our ability with a patent law that fires rather than deadens incentive. Your bill protects industry in its rights as does S. 789 to some extent, but S. 1899 would be duplicating at the taxpayer's expense such research activity that could and should be carried on by industry and other private agencies.

I should like these remarks made a part of your hearings record; i.e., that of Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary.

Sincerely,

C. A. VANDERWERF,
President of Hope College, Professor of Chemistry.

WESTERN ELECTRONIC MANUFACTURERS ASSOCIATION,
Palo Alto, Calif., July 30, 1965.

Hon. JOHN MCCLELLAN,
Chairman, Senate Judiciary Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: I am taking this opportunity to write to you to express the viewpoint of the Western Electronic Manufacturers Association regarding the proposed legislation on patents pending before your subcommittee.

The Western Electronic Manufacturers Association is a trade association of companies engaged in electronic manufacturing or electronic research and development in the 13 Western States. Our total membership today is 360 companies. These range in size from small companies to large corporations.

Some of our member companies employ many thousands of persons and have been important prime contractors in the Government's defense program. However, the majority are smaller firms which have served as subcontractors or component suppliers. These companies are technologically based and dependent upon their individual inventiveness and improvements in the state of the art to maintain a position in this competitive market. Accordingly, our association has a vital interest in the subject matter of the vesting of patent rights developed under research and development contracts with the Federal Government.

For some time we have been opposed to Senator Long's unequivocal position that the Government should be entitled to exclusive patent ownership. His pending bill S. 1899 ignores the fact that if American industry is to apply its accumulated technology and know-how in the solution of developmental problems, it must be afforded patent protection to maintain viability and be of even further service to the Government. Moreover, the incentive of attaining a proprietary position must be offered to stimulate the growth of small business.

Senator Saltonstall's bill S. 789 presents a much sounder understanding of the respective needs of Government and private industry, and equitable patent legislation could be built on the fundamental points set forth.

We heartily endorse S. 1809, which you introduced, because it is a well-developed bill which recognizes the equities of the joint effort by industry and the Government under research and development contracts. As in the statement of patent policy issued by the President, this bill analyzes the several situations which can exist and establishes equitable criteria for distribution of any resulting patent rights.

However, we suggest that the bill be strengthened to establish definitive rights at the time of contracting to give a potential contractor greater assurance of protection in the area of self-developed technology. Perhaps some of the language of S. 789 might be helpful in this regard.

We also feel that the bill should be expanded to insure the protection of inventions from foreign exploitation.

Thank you for the opportunity to present this statement in behalf of the Western Electronic Manufacturers Association.

Sincerely,

W. H. HEFLIN, *President.*

WESTINGHOUSE ELECTRIC CORP.,
PATENT DEPARTMENT,
Pittsburgh, Pa., May 14, 1965.

S. 1809 (McClellan).

Hon. JOHN L. MCCLELLAN,
U.S. Senate,
Washington, D.C.

DEAR MR. MCCLELLAN: We have studied carefully S. 1809 dealing with the disposition of rights to inventions made under Government R. & D. contract.

We believe that the objectives sought are sound and that the approach taken is such, generally speaking, that substantial benefit should result to the general economy, the Government, and contractors if the subject bill should be enacted into law and administered reasonably.

It would only be natural, I suppose, that we would prefer some changes in specific language. We, therefore, take the liberty of suggesting some major points where we think confusion may arise or problems may develop in administering the bill if it should be enacted as introduced.

Referring to section 3(b)(5), the determination of reasonable terms and conditions, and, perhaps, the granting of compulsory licenses is placed in the hands of the agency involved. It would seem to us that it might be advantageous from the Government standpoint as well as from the public benefit that the agency head do no more than "supervise" the granting of such licenses. In this manner, the burden would be transferred from the agency head to the contractor in an area where we believe the contractor would be more than happy to assume the burden. It is suggested that lines 3 to 11 be revised as indicated in the following wherein insertions are underlined and deletions are lined out:

"terms and conditions *subject to review by* ~~as~~ the agency *head* ~~may prescribe~~ upon a determination made by such agency head, after affording the opportunity of a hearing to the owner of those rights, that (a) the owner of those rights has not exerted substantial efforts to bring the invention to the point of practical application and (b) the public interest would be *better* served by *requiring the owner to license one or more* ~~the issuance to~~ other persons ~~of licenses for the~~ *to* practice ~~of~~ that invention;"

Referring to section 3(b)(8), we note that there is no excuse whatsoever permitted for failing promptly and fully to report an invention. In view of the serious penalty; i.e., forfeiture, involved and because reasonable men can well differ on reasonable time for reporting as well as whether reporting is required, we would urge that, in line 12 on page 6, there be inserted after the word "knowingly" the words "and in bad faith". In support of the above suggestion, it is noted that conceptions and first actual reductions to practice form the basis for reporting of inventions. As a quick glance through board of interference and court decisions on interference situations will disclose, it is often not easy to determine when a conception has been made and when an actual reduction to practice has been made. Many interferences and court cases hinge on these determinations and, since there is usually involved a question of judgment with respect to which attorneys will differ, it is believed that a sort of "rule of reason" should be applied in this area and that severe penalties should not be enforced unless an element of fraud is present.

Referring to section 4(a), the proposed bill provides that the "agency head shall acquire" certain rights. It may be that the rights involved are not worth acquiring and it may be useful from the standpoint of economics, if for no other reason, that title be avoided and the necessity of, or at least a decision concerning, the filing of patent applications be avoided. You might like to consider inserting in line 20 on page 6 after the word "shall" the words "reserve the right to".

Referring to section 4(a), and more particularly to the criteria identified as justifying the taking of principal rights, there are certain ambiguities or at least certain degrees of indefiniteness which, in our opinion, are likely to cause future problems.

Referring to subparagraph (1), it would seem to us of doubtful value for the Government to acquire title to all inventions made merely because the invention

may be required for use by governmental regulations. In this connection, we would distinguish, for example, between a contract having as an object an improvement or cost reduction or some other minor modification of a well-known drug such as "aspirin" as distinguished from research directed to a significantly important medical advance such as a cancer cure. The same approach is applicable to subparagraph (2) where you might distinguish between an improvement in stair treads to minimize the danger of slipping as compared with a device for absolutely preventing collisions between vehicles. To soften the impact on contractors without disadvantaging the public, both of these criteria might be restricted to improvements or inventions of critical significance in connection with the end objective.

Thus, referring to section 4(a)(1), we suggest inserting in line 8, page 7 after the word "regulations" the words "provided that such products, processes, or methods are of critical significance and that no reasonably competitive item is readily available."

In line 5, page 7 (sec. 4(a)(2)), we urge insertion following "concern" the words "and are of critical significance in connection with."

Further, with respect to section 4(a)(2), the word "welfare" is so general as to be indefinite; we recommend deletion of that word.

Referring to subparagraph (3) under section 4(a), there will certainly be some difficulty in determining whether the Government is the principal or prime developer of a field. For this reason, we would urge consideration of limiting the application of this subparagraph to those situations wherein the Government has been "substantially the sole" developer.

Again, in this same subparagraph, the Government may acquire greater rights whenever the invention "might" confer on the contractor a "preferred or dominant position." It can be argued and has been argued under the present DOD regulations that every patent confers a preferred position. Indeed, this is the purpose of the grant of a patent. It is not this sort of preferred position which you have in mind, I am sure, and, similarly, others who have proposed this type of language have not had this kind of dominance in mind. Therefore, it is believed that it would be helpful to reword this criterion as follows:

"rights at the time of contracting is likely to confer on the contractor a dominant position;".

Referring to section 7, we note the possibility that the agency head may direct the issuance of a patent to the Government in situations where the contractor has already filed a patent application. We would urge consideration of suitable reimbursement to the contractor in such a situation.

Referring to section 8, we would anticipate considerable protest or at least adverse comment concerning the requirement that agency heads shall affirmatively protect and preserve the property rights of the United States in patents owned by the United States. It could be argued that the property right carries the privilege of protection and preservation and, therefore, it would be better not to insist that the Government prosecute U.S. citizens for using patents issued for the benefit of the U.S. public at large.

With respect to section 8(b), it is noted that the agency head cannot in fact grant an exclusive license because the contractor is granted a reserved nonexclusive license and presumably the Government should retain a nonexclusive license for its own governmental operations. In this area, i.e., exclusive licensing, we would urge a careful study be made because, at first thought, it appears to be repugnant to argue that the public benefit requires the taking of exclusive rights from the contractor only to, in turn, pass on those exclusive rights to another citizen or U.S.-based firm. It is for this reason that many believe that any citizen who wishes to use a Government-held patent should be entitled to a free, nonexclusive license.

Referring to lines 10 and 11 on page 15, the license provided therein may be granted with or without the payment of royalty to the United States. Some of us fear that this type of language can lead to governmental regulation of industry by determining who can have a license and how much he may have to pay. It has been advocated, for example, that the Government grant exclusive licenses to a small company to help it grow larger and then when it is large enough to stand on its own feet, the license would be taken away and given to someone else or the royalty rate would be increased or some other step taken to

remove any advantage it might have. Many fear this type of Government entry into the control of the business of the Nation.

Referring to section 9, provision is made in subsection (b) that a report and summary of findings be made with respect to those inventions wherein the agency involved has acquired no greater rights than a royalty-free license. No such reporting is required when title is taken. In order to avoid the burden of making reports under license situations, contracting officers may well have a tendency to press for taking title wherever possible in order to avoid this reporting function. Moreover, for the reports to be of greatest value to Congress, it would seem that similar reports should be made with respect to situations where the Government has taken the principal rights. For example, such reports would be valuable in determining whether the various agencies are reasonably applying the various criteria. Therefore, we would suggest the insertion of a subsection reading as follows:

"The number and general nature of such inventions with respect to which the agency acquired greater rights than a royalty-free license in accordance with section 4 and a summary of the findings of fact upon which a determiantion of the applicability of sections 4(a) (1), (2), (3), or (4) was based."

We sincerely hope that the foregoing will be of some assistance to you.

Very truly yours,

T. L. BOWES,
General Patent Counsel.

LONDON, *July 3, 1955.*

Senator JOHN MCCLELLAN,
Senate Subcommittee on Patents,
Washington, D.C.:

I regret my inability to appear in person before your committee for I spent many months during my term as President Kennedy's science adviser exploring facets of Federal patent policy. Sound Government policy must be flexible enough to satisfy both private and public interest to provide maximum availability of invention and technology for defense, and maximum incentives for economic development as well. The patent policy memorandum of October 10, 1963, reflected a careful effort to balance these requirements. It was the product of coordinated study of the Government agencies which must enlist contractors to perform their functions and had the endorsement of those agencies.

McClellan bill S. 1809 would implement this balanced and equitable policy, if possible, I would appreciate having my 1963 testimony and responses to questions before Senator Long entered as testimony for your hearings.

J. B. WIESNEN,
Dean, School of Science, MIT.

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