

NJL

December 20, 1977

Mr. Raymond Woodrow
P. O. Box 36
Princeton University
Princeton, NJ 08540

PATENT BRANCH, OGC
DHEW

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Dear Ray:

Enclosed is a copy of the draft letter we discussed. Also enclosed is a copy of Senator Nelson's remarks opening the recent hearings.

I would appreciate receiving a copy of any letter that you or SUPA send out on this subject.

Sincerely yours,



Jesse E. Lasken
Assistant to the General Counsel

Enclosures

bcc: ✓ Norm Latker

Dear Mr. Chairman:

I am writing one behalf of the _____ to express my dismay at the tone of your recent press release announcing hearings by Senate Select Committee on Small Business on the subject of Government patent policy.

~~_____ and distorted _____ of _____ of _____~~
~~_____ into question.~~ I am also concerned and believe it necessary to bring to your attention that Mr. Gordon of your Committee staff, who appears responsible for these hearings, refused to allow representatives of the university community to testify, and, indeed, misrepresented to Mr. _____ Woodrow, President, Society of University Patent Administrators, that only witnesses from within the Government would be called, a fact belied by the actual witnesses. It is my understanding that he did the same to representatives of the small business community.

I can only attribute the distortions and misunderstanding displayed in your release to the zeal of certain persons on your staff ^{who} seemingly in the name of competition, would have the Government establish a set of policies which on careful reflection would be found to have the opposite effect, would be detrimental to economic growth, would be detrimental to the interests of the small business community, would probably work to the benefit of state subsidized foreign corporations to the disadvantage of American labor and business, would lead to increased administrative costs, and which might prove detrimental to the conduct of the national defense effort. Members of your staff are apparently content to substitute slogans for analysis, dogma for reason, and distortion for fact.

I know of no other way to explain the fact that your staff would have you claim that a 1924 Attorney General opinion, which did not even address the legality of exclusive licenses, held against them. I also do not know why they neglected to inform you that just a few years ago the Justice Department concurred in the current Federal Property Management Regulations governing licensing of Government-owned inventions which recognize the propriety of exclusive licenses.

For reasons best known to himself, Mr. Gordon chose to specifically identify among these agencies considered "culpable" the Defense Department, the Department of Commerce, and the National Science Foundation. Since NSF primarily funds university research and since most of the members of SUPA have generally found NSF's policies to be reasonable and deserving of emulation by other agencies that support university research, we consider an attack on that agency's policies as an attack on the integrity of those institutions that NSF has allowed to retain rights to inventions.

Your press release states that NSF "automatically give(s) away almost all Government rights to the firms that engage in government-supported research." If Mr. Gordon had been at all interested in the truth, he might have taken the time to determine the veracity of this as well as other portions of the release. NSF regulations and practice is to normally include in its grants a clause giving the Foundation the right to determine the disposition of any inventions after the invention is identified. A few universities with active technology transfer programs have entered into Institutional Patent Agreements with NSF which normally allow the university to retain principal

retain principal rights to any inventions. However, on occasion, for reasons not always too clear to those of us at the universities, NSF sometimes exempts specific grants from the operation of these IPAs. Universities that request rights from NSF under a deferred determination clause are required to supply supporting information. It has been our experience that in most cases NSF grants such requests.

The terms of the NSF IPA's and their deferred determinations are substantially the same and belie the statement that "almost all government rights" are given away. If anything, we feel that NSF terms are overly cautious and restrictive. Assignment of inventions except to approved patent management organizations is barred. Except with NSF approval, we cannot grant exclusive licenses which exceed the earlier of eight years from the date of the license or three years from first commercial sale. NSF retains a license for Federal, State and local government use and takes the usual Government march-in rights.

We presume that the reason that NSF enters into IPAs or normally allows requesting universities to retain rights in identified inventions is that they understand, as Mr. Gordon apparently does not, that without the incentives provided by the granting of such rights the universities would have little incentive to seek licensees and potential licensees would be unwilling to invest in the development of these inventions. Indeed, neither NSF nor other agencies would normally fund the type of development and marketing work that is required to commercialize an invention.

We would challenge Mr. Gordon or anyone else to produce a single example of a case when someone has made so-called "monopoly profits" on any invention in which NSF (or other agencies for that matter) have left rights in a university (or other contractor). The real problem is not "monopoly profits," but finding a way to induce private investment in the further development of inventions and to get them into the market place at all.

We also defy Mr. Gordon to produce ^{de} a single example of a case in which allowing a university to retain rights has had the effect of deterring or inhibiting the further development of any invention.

I doubt that this letter is the best vehicle for discussing the overall issue of Government patent policy. And I am obviously in no position to speak for NSF or other Government agencies. But I think for the most part that ^{the} consideration and concerns that I will outline below are shared by many other people who have attempted to approach the issue with a view towards the overall ramifications of its resolution. For example, for reasons developed later, I would submit to you, as a perhaps somewhat over-dramatic example, my conviction that a patent policy that required the Government to retain title-to-inventions would have the likely effect of retarding or eliminating altogether the development and marketing of some potentially life-saving drugs.

On a broader scale, I also believe that a closer examination ['] than is manifest in the press release of the concept of "competition" is needed if this issue is ever to be properly resolved. A better understanding of the dynamics of competition and economic growth is sorely needed. Typically discussions of "competition" are centered around a given product and concern

the factors that will result in or deter competition in a given industry. Unfortunately, these classical modes of analysis, while useful in some contexts, have some important limitations. In particular, they do not really explain the form of competition that truly allows our economy to grow and which prevents it from becoming even more oligarchial than it already is.

I submit to you the proposition, which is by no means original with me, that the key to economic growth and competition in this country is the introduction of new products and new technologies--in other words innovation. I believe it was Joseph Schumpeter who terms^d this "the gale of creative destruction." I would ask whether anyone would seriously contend that our economy, indeed our political freedoms, would not be in serious trouble if, for example, in 1977 we were still producing the same products as we were in 1930 or 1950 or even 1960. If that were the case our economy would have truly stagnated, all the Government policies in the world would not have prevented the concentration of numerous industries in the hands of a few large companies, and this Nation would be in serious trouble.

I am not so naive as to believe that Government patent policy is the only factor that will affect innovation. But with over half of the research done in this country being supported by the Government, we had best understand the affect of Government patent policy on the transformation of the results of that research into new commercial products and processes. I cannot tell you that a Government patent policy that provides for or favors title-in-the-Government would bring about the stagnation that I have described, since many other factors are at work. But I am convinced that such a policy will tend in that

direction. And I am especially certain that it would have negative effect on the development of inventions made at the universities.

As stated earlier, I believe it useful to give a concrete example of the real impact Government patent policy can have. It could be argued and I would agree, that anyone can make up hypotheticals to prove that one policy is superior over another. Of course, I believe that the hypotheticals that I would cite are much closer to real life and more typical of it than those that Mr. Gordon or his allies would be forced to use. But leaving that aside, this example is not intended to be taken as a model of all Government R&D or all industry. It is meant, though, to illuminate in a very real way how adoption of a "title-in-the-Government" approach would inevitably result in a most unfortunate result. I think you will also find that a fairly significant number of university inventions are of the type I will discuss.

A significant part of the research budget of the United States goes towards medical research and related fields such as biology or chemistry. Out of that research, new compounds are often synthesized in university or other laboratories. However, it is one thing to develop a new compound in a laboratory and another to determine whether it has pharmaceutical potential and, if so, how much potential, in what formulation and dosage, and with what side effects. The compound must be screened, tested further, and tested clinically. An economical means of mass production may need to be developed. Its utility has to be brought to the attention of physicians, and a means of distribution is needed. These necessary and costly tasks, all of which takes place after the laboratory synthesis of the compound, are now almost

exclusively performed not by the Government but by the drug industry. Leaving aside arguments over whether drug companies make too much money or improperly advertise or push some drugs, it ought to be quite clear, whether or not some internal reforms are needed, that without drug companies we will not have drugs. Experience, as well as common sense, should tell us that any given drug company is not going to engage its limited resources in the costly process of commercializing a new compound invented under someone else's Government grant or contract which its competitors can then market and replicate without going through much of the research performed by the first company. This is not to say that being first or other factors might not overcome the disadvantage of extra costs. But in making the initial decision to invest one cannot know with certainty what the ultimate facts will be. And often one could decide to rely on nonpatent factors only after some initial investment. We could, for example, hypothesize that a drug company might screen a nonpatented compound and do some initial testing, and based on that decide that the market potential is so high that they will go ahead regardless of patent rights. On the other hand, the market may be such that it would be unprofitable to proceed without exclusive rights. If you happen to be the unlucky soul^o who suffers from a relatively rare disease, it will probably be of little interest to you that the reason a known cure did not get produced was because it was made unprofitable by^a Government patent policy supposedly designed to foster competition.

But, of course, the example given above hypothesized that the company was willing to undertake some initial screening and testing before making a decision. Again, while that makes an ideal hypothesis, in real life

it seems apparent that drug companies do not behave that way. The managers of these companies seem to find it more to their advantage to concentrate the development efforts of these companies on compounds which they can protect and control.

What I am saying is that if you will look beyond slogans and passions and attempt to address the real manner in which the pharmaceutical industry operates you will find quite literally that a title-in-the-Government policy is going to have the tendency of condemning some person either to needless suffering or an early death because the commercialization of some compounds was made too risky or unattractive for private industry to undertake. I think you will also find if you really analyze the situation critically that it confounds reason, experience, and reality to believe that a title-in-the-Government policy will have the redeeming benefits of lowering the prices of other drugs or of leading to the development of some drugs which would not have been developed if the inventing contractor held patent rights.

Hopefully having impressed upon you that we are dealing with an issue whose resolution can have profound impacts, I urge you to open your mind and to be willing to engage in a detailed and realistic analysis of the issue. This issue must not be resolved through slogans or rhetoric. All of us must be willing to examine rationally and in some depth the realities of the situation and the likely results of alternative policies.

In your remarks opening the hearings in question, you stated that your committee would examine three problems. Unfortunately, these issues are

worded in such a way as to make it apparent that the author has prejudged the resolution.

For example, you first state that "there is a problem of increasing economic concentration brought about by the granting of patent monopolies to individual firms for discoveries which result from Government-financed research and development contracts." What evidence do you have that the retention of rights in any inventions by Government contractors has led to increased concentration of any industries? How do you know that Government patent policies have in any way contributed to the concentration of any industry? Is the nuclear energy industry any more or less concentrated because the Government retains rights in that area?

Next you seem to be saying that Government patent policies that leave inventions in contractors may favor larger firms that get the bulk of Government contracts. Actually, if the matter were analyzed carefully one would probably find that the competitive position of small firms vis-a-vis ~~a~~ larger competitors ^{are rarely} would not be affected by ~~a~~ larger firms being allowed to retain rights to ~~an~~ invention, ~~it~~ made under ~~a~~ Government contract. You would probably find that in the vast majority of cases the dominance of the larger firm is a function of financial resources, economies of scale, access to resources, and marketing and distribution systems with which smaller firms cannot compete regardless of the patent situation. Conversely, you would find that smaller firms are much more dependent on patent protection to maintain their position in the specialized areas that they carve out for themselves. Thus, if the Government takes title to inventions made by small firms under

Government prime or subcontracts their competitive position can be put in jeopardy since larger firms would then be able to make use of the invention, and the smaller firm would not be able to obtain the protection of patent rights. And we must assume that trade secret protection is ruled out since the results of Government supported R&D would normally be made available to the public.

Moreover, you would probably also find that small business would be placed at a greater disadvantage in competing with larger firms for Government contracts under a title-in-the-Government as opposed to a title-in-the-contractor policy. Large firms, that are less dependent on patents to maintain their positions, will probably be more willing to compete for and accept Government prime and subcontracts regardless of who gets the rights. Thus, a title-in-the-Government policy would probably have the effect of adding to the already heavy concentration of Government R&D funds in a few large firms.

Next you stated "there is a problem of assuming that newly acquired technological information developed at Government expense and not of a classified nature is diffused throughout our society. The American people foot the bill. Do they receive commensurate benefits from this work?" This is a fair question, and it should be one of the primary focuses of any inquiry into Government patent policy. What I think many of us are trying to say is that the public will not get "commensurate benefits" if the Government insists on acquiring rights to inventions and thereby destroys the incentive, in a significant number of cases, for private

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companies to invest in the further development of these inventions. Indeed such a policy may favor state subsidized foreign firms that can afford to develop inventions because of advantages afforded them by their Governments that have nothing to do with patents.

American which they learn about through the literature or at conferences, etc.

Finally, as a variation on the prior question, or perhaps as an answer to it, you ask "Is the Government giving away more than it should in the granting of its R&D contracts? Is it possible to recover part, or perhaps all, of our expenditures on research and development?" This question again raises the "give away" spector. One could just as well ask whether the Government is "taking away" too much in its R&D contracts. We should be attempting to determine which policy or combination of policies will best promote economic growth, competition, the defense needs of our country, or other objectives that may rationally be shown to be influenced one way or the other by patent policy. Let us attempt to judge these matters through reason and analysis and not by value-laden slogans.

I and I am sure many other persons who do not agree with Mr. Gordon's views would be more than willing to testify before your committee if you decide to hold further hearings. However, I would be less than candid if I did not tell you that my organization would prefer that your Committee not hold further hearings since events to date strongly indicate that the Senate Select Committee on Small Business is being used simply as a sounding board to air the views of Mr. Gordon, and not as part of any rationale process to arrive at balanced conclusions and recommendations concerning Government patent policy.

I request that this letter be made a part of the hearing record.

Respectfully yours,

cc: Members, Senate Select Committee on
Small Business

bcc: Mbrs of organization sending ltr
and other university groups.
NSF Oversight Cmte Mbrs