Analytical Basis for The University Position on H.R. 8596

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Table of Contents

ANALYTICAL BASIS FOR THE UNIVERSITY POSITION ON H.R. 8596

<u>Section 1. Optimum Patent Policy - a National Viewpoint</u>	
Objectives and Alternatives Policies 1	
A Comparison of the H.R. 8596 and Title-In-the-Government Approaches 2	
(1) The Impact of Patent Policy on Competition	
(2) The Impact of Patent Policy on Innovation	
(3) The Impact of Patent Policy on the Public Health 12	
(4) The Impact of Patent Policy on Economic Growth and Jobs 14	,
(5) The Impact of Patent Policy on Foreign Competition 15	
(6) The Impact of Patent Policy on Contractor Participation 17	
(7) The Cost of Administering Alternative Patent Policies 19	
A Comparison of the H.R. 8596 Approach with the Case-by-Case Approach 20	
(1) Administratsive Costs 20	
(2) Contractor Participation 21	
(3) Foreign Competition 21	
(4) Public Health 21	
<pre>(5) & Economic Growth and Innovation 22 (6)</pre>	
(7) Competition 24	
<u>Summary</u> 27	
Section 2. Considerations Affecting Government Patent Policy as it Pertains Specifically to Universities	;
Section 3. Problems with the "Status Quo" 29	ł

Page

THE UNIVERSITY POSITION ON H.R. 8596

Section 1. Optimum Patent Policy - A National Viewpoint

Objectives and Alternative Policies:

To arrive at a proper Government patent policy, one must understand the impact that alternative policies can have on various objectives that can reasonably be expected to be affected by patent policy. We believe patent policy should be judged by its impacts on the following: (1) competition, (2) innovation, (3) public health, (4) economic growth and jobs, (5) foreign competition, (6) contractor participation, and (7) the administrative costs entailed by the policy.

Many of these objectives are interrelated, but each, we believe, needs to be clearly understood, recognized, and weighed in arriving at conclusions concerning proper patent policy. We hope, therefore, that we will be forgiven if in places our discussion appears repetitive.

There appear to be three major approaches to Government patent policy. These are:

(1) The H.R. 8596 Approach. Under this approach as a normal rule contractors or grantees would be allowed to retain title to inventions made under the award subject to a Government license and "march-in" rights. In individual cases, agencies could use deferred determination or other more restrictive clauses.

(2) <u>Strict Title-in-the-Government</u>. Under this approach, as a condition of receiving a Government research grant or contract, the contractor would have to agree to transfer rights in all inventions made under the contract to the Government. The Government, in turn, would either dedicate the inventions to the public or license them itself. Assistant Attorney General Shennefield in his testimony on December 20, 1977, before the Senate Select Committee on Small Business stated that this is the policy preferred by the Justice Department.

(3) <u>A case-by-case approach</u>. Under this approach individual agencies would select the patent clause to be used in each grant or contract on a case-by-case basis, and agencies would also in many cases delay the determination of whether contractors would retain rights until after inventions have been identified. Depending on the exact manner in which the policy is framed there may or may not be presumptions in favor of or against the taking of title by the Government. The recent ERDA legislation is an example of such an approach. It places the presumption in favor of the Government's taking title, but gives ERDA considerable flexibility to decide otherwise depending on ERDA's evaluation of a variety of factors. In reality, this type of approach, which some claim represents a middle-ground, is not a uniform policy at all since agency practices will vary considerably depending on the predilections of agency officials involved in the process.

We have organized this discussion to first consider the impacts of the first two alternatives on the various objectives that we have listed. We believe it will facilitate understanding of the issues and the considerations involved if one first compares in isolation the differences between the H.R. 8596 approach and a title-in-the-Government approach. After this comparison, we then analyze whether the case-by-case approach has any advantages or disadvantages as compared to the H.R. 8596 approach (which our analysis shows to be superior to a title-in-the-Government approach.)

A Comparison of the H.R. 8596 and Title-in-the-Government Approaches.

Before beginning our analysis, we offer an observation that should be recognized by Government policy makers. That is, persons who favor a titlein-the Government patent policy appear to advocate this position primarily on the basis of a belief that allowing contractors to retain title will be anticompetitive. To the extent the other objectives of Government patent policy are considered, it is argued that there is no evidence to support some of the effects others consider relevant such as the impact of patent policy on innovation or contractor participation. It would thus seem that Federal policy makers should support an H.R. 8596 approach to patent policy if the contention that H.R. 8596 approach is anticompetitive can be shown either to be wrong or questionable. We believe that it can reasonably be demonstrated that every other objective of Government patent policy will be more clearly fostered by an H.R. 8596 approach than by a title-in-the-Government oriented approach. For this reason, we will begin our analysis with a review of the impact of Government patent policy on competition.

(1) The Impact of Patent Policy on Competition

In our estimation a title-in-the-Government policy would, on balance, prove anticompetitive as compared to the H.R. 8596 approach.

Before detailing our reasons for making this statement, we think it useful to emphasize that the introduction of new products and processes into the market place is a key factor in maintaining a competitive economy. However, much of the classical economic analysis of competition is based on analysis of a static rather than a dynamic model. While such analysis is useful in many circumstances, we question whether it is the best model to use in evaluating Government patent policy. We believe that the economic health of the nation, long-term economic growth, and the maintenance of competition is much more dependent on stimulating the introduction of new products and technologies than it is on ensuring maximum competition in the manufacture and sale of a given product.

With this in mind, let us examine critically the argument, which seems to be based on the static model, that a title-in-the-Government policy will promote competition. The supposition that seems to underlie this argument is that most Government contractors are large, dominant firms and that if they are allowed to retain rights to inventions their dominance will be enhanced. 1/ Retention of "march-in" rights are apparently not deemed sufficient to prevent this. Following this approach, of course, necessitates also taking rights from smaller firms and universities that deal with the Government. However, it is argued that since these firms do a relatively small proportion of Government contracting, it is not worth worrying about the few inventions they make as compared to the great number coming out of the large firms. 2/

- 1/ Assistant Attorney General John Shenefield, in advocating a title-in-the Government approach in his appearance of December 20, 1977, before the Select Committee on Small Business, U. S. Senate, stated, "The competitive risk to the public in transferring title to the contractor may be especially high where transfer carries a danger of further entrenching the already strong market positions of many Government contractors."
- 2/ For example, Admiral Rickover, a leading proponent of the title-in-the-Government approach, in his statement of December 19, 1977, before the Select Committee on Small Business, U. S. Senate in questioning the wisdom of allowing contractors to retain rights stated, "Since large corporations get the major share of Government contracts, they would be the ones to benefit most from such a practice." Later, he claims, "Small business, for its own advantage, should be against a giveaway patent policy. The vast proportion of Government financed inventions are given away to contractors, the Government itself will be promoting the concentration of economic power in the hands of a few large conglomerates."

As an initial observation, we note that a substantial portion of Government R&D is conducted by universities and other high-technology commercial firms that are not dominant in any commercial markets. Even when Government prime contracts for major systems development are awarded to major corporations, some of the work is subcontracted with the result that some of the new and innovative ideas stem from lower-tier subcontractors. It is extremely unlikely that dominant firms receive even half of the total Federal extramural R&D budget. 1/

We also believe it likely that a substantial portion of Government R&D that goes to firms that are dominant in commercial markets would be found to be with major air frame and engine manufacturers that dominate both the Government and civilian markets in this area. It ought, however, to be fairly obvious that whether or not the Government takes title to the inventions of these companies the effects on competition in these capital intensive industries will be negligible. Indeed we would note that until the Justice Department recently took action to end this, there was a policy of cross-licensing within that industry which made inventions generally available.

Whatever may be the exact distribution of the source of inventions made under Government contracts and grants, in the case of those inventions made by dominant firms one would find that in the vast majority of cases those firms' positions would not be affected vis-a-vis other U.S. firms by the disposition of rights in their inventions. Patents would probably be found to be of minor consequence in the maintenance of dominance in their industries (although in some cases they may have been an important factor in the early growth of the firms.)

The NSF Surveys of Science Resources Series, NSF 77-301, Vol. XXV, 1/ "Federal Funds for Research, Development, and other Scientific Activities," estimates that out of a total federal budget for basic, applied, and developmental extramural research in FY 1977 of \$17.428 billion, 30% was performed by universities and other nonindustrial performers. And in the sub areas of basic and applied research the industrial share was only around one-third. These statistics do not, however, provide any breakdown between the types of industrial performers, i.e. what percentage were small businesses. A recent draft study by the Office of Federal Procurement Policy finds that in FY 1975, 7.8% of federal R&D awards to industry from major agencies went to small business. However, this study covers only prime contracts and does not indicate the percentage of prime contracts to large firms that were subcontracted to small firms. It would also seem unlkely that all of the nonsmall business industrial firms dominate or control a substantial share of their commercial markets. Hence, at a minimum around 35% of federal extramural R&D is performed by small business and nonindustrial institutions. Thus, it would be most unlikely that dominant firms actually receive even half of the total R&D extramural budget.

In most cases superior financial resources, economies of scale, access to resources, and well-developed marketing and distribution systems will be found of much more consequence to the maintenance of dominant firms market position. These are the factors that prevent new firms from entering the market and which prevent smaller firms from effectively competing and increasing their share of the market. Even if the Government took title to inventions of dominant firms, we believe that in most cases the factors listed above would prevent smaller firms from making any effective use of the inventions, the great bulk of which, in any case, are merely minor improvements on existing technology controlled by the inventing firms. 1/

Conversely, smaller firms do not enjoy the advantages described above. For such firms, patent protection is a much more significant tool. When a smaller firm makes a new invention that has the potential of being developed into a new product which might increase that firms share of the market, patent protection may be the only defense that that firm has to prevent larger firms from undercutting its market. Without patent protection, larger firms could, because of the advantages noted above, undercut any market developed by the smaller firms.

Thus it appears to us that a title-in-the-Government policy will have, at most, a marginal effect on the market position of already dominant firms, but that it will almost surely destroy the competition that might result from smaller firms developing inventions coming out of Government work.

There is another major shortcoming with the proposition that taking title from dominant firms will allow other firms to use the inventions so as to increase competition. First, it seems likely that the number of inventions reported to the Government would decrease if contractors saw no advantage to reporting them. Second, it is unclear just how other firms would learn of those inventions that were reported. Typically, invention reports come in as separate items or addendums to progress reports. As far as we are aware there is no systematic publication of reported inventions, per se, by the Government, and even if there were it is doubtful that this would be an effective means of achieving technology transfer of specific inventions. The closest approach currently available is the NTIS publication of Government-owned inventions available for licensing. However, publication, unless it is combined with other techniques, is not really a particularly effective way of alerting and interesting commercial firms in inventions (even if one assumes such firms would be willing to invest without exclusive rights). In the next subsection, we also note other limitations of a Government-licensing approach.

1/ While we agree with little else that Admiral Rickover has to say on patent policy, we are in agreement with his observation in his December 19, 1977, statement to the Senate Select Committee on Small Business that "Large corporations file numerous®patents that are not great new developments, but minor improvements or design features." We would also have the reader note that even to the extent that taking title from dominant firms will increase competition, the sources of competition may turn out to be , not American firms, but foreign, state-supported corporations. This is discussed in somewhat more detail in subsection (5) below. Finally, at the risk of seeming repetitious, we remind the reader that the foregoing discussed the effect of patent policy on a static model of competition. Over the long-run innovation may be a major factor influencing competition. Accordingly, the discussion in subsection (2) is closely related to the subject of this subsection.

(2) The Impact of Patent Policy on Innovation.

Let us now consider the impact of patent policy on innovation. By innovation we mean the conversion of inventions made with Government support to commercial products and processes. In line with our attempt to consider separately each of the objectives of patent policy, the following discussion attempts to isolate the innovation objective from the competition objective. Accordingly, for the purposes of this subsection, we consider it irrelevant whether commercialization of a given invention is accomplished by one firm or multiple firms or by large firms or small firms. Instead, our analysis is intended to address only whether the chances of inventions being developed by anyone will be enhanced or diminished by one approach or the other.

It should be clearly understood that many inventions that are reported under Government grants and contracts are by-products of the research being supported. This is certainly true of almost all university inventions. Similarly, very rarely does the Government support research and development to the point where a given product intended for the commercial market has been proven both technically and economically feasible so that private firms would view investment in the manufacture and marketing of the product as virtually risk-free. And even where a Government contract does have this objective, many of the inventions reported under that contract may still be by-products of the research or may have potential uses in areas not being tested by the Government. In those cases where the Government is supporting full development, H.R. 8596 would leave the agency with the discretion to use a deferred determination or other more restrictive patent clause.

However, in the great bulk of cases, H.R. 8596 would result in agencies allowing contractors to retain rights. In such cases will allowing contractors to retain rights more effectively stimulate innovation than a titlein-the-Government policy? We believe the answer is clearly "Yes." Given the fact that the vast majority of Government-supported inventions have not been developed beyond the laboratory stage and will not be through Government support, it should be obvious that substantial private investment will be needed to bring the invention to the market. One estimate made several years ago was that the cost of bringing an invention to the market entailed, on the average, about 10 times the cost of inventing it. 1/ Experience at many universities bears this out. The amount of Government support actually involved in a grant or series of grants that lead to an invention is usually small in comparison to the estimated costs that licensees would have to invest to develop the invention to the point of commercial application. It has also been our experience that it is relatively rare for a firm to be willing to invest in the development of a university invention without being afforded some exclusivity. We would bring your attention to the report of the Ad Hoc Subcommittee on University Patent Policy (copy attached) which develops more fully than we will in this paper why this is the case.

Similarly, in the case of inventions made directly by smaller firms under Government contracts or subcontracts, we find it difficult to believe that such firms would normally be willing to invest in the further development of the invention without exclusive rights.

In the case of larger firms the impact of the Government's obtaining patent rights on their inventions on their willingness to invest in the development of those inventions is less clear. It is certainly indisputable that many firms, especially in certain industries, would not invest without exclusive rights, and neither would any other firms with the possible exception of certain foreign firms that enjoy state-supported monopolies (having nothing to do with patents) in their home markets. On the other hand there would undoubtedly be some cases when larger firms would work their inventions even without exclusive rights. Minor improvements might get integrated into on-going product lines. And new products might be developed by larger firms where the market potential was clear.

1/ U.S. Panel on Inventions and Innovations, "Technological Innovation: Environment and Management, pp. 8-9 (GPO, Jan. 1967). Our conclusion that leaving title in contractors is much more likely to result in commercialization than is the Government's taking title is supported by the data developed by Harbridge House, Inc. in its 1968 study. For example, Harbridge House examined all Government-supported inventions patented in 1957 and 1962. Of all the inventions utilized in this group, they found that the contractor held title to 203 and the Government to 7. In the total sample the Government held title to around 27% of the inventions. Harbridge House also found, "Of all the factors patent rights and prior experience show the strongest association with commercial utilization." The Harbridge House analysis indicates that all other things equal a firm with title is about twice as likely as a firm without title to commercialize an invention. It can also be documented that in the overwhelming number of instances in which universities have obtained licenses for their inventions an agreement could only be consumated on an exclusive basis.

It thus seems clear that the result of the Government keeping title will be to deter investment (innovation) in some cases, and to have a neutral effect in others. The only question that remains is whether this might be counterbalanced by some larger firms using their patent rights to suppress or defer the development of inventions that others might have been willing to develop had the Government held title. We believe such fears are largely unfounded and that, in any case, even if the Government held title the likelihood of other firms developing most inventions would be small. Even if the Government held title in the invention, it can be questioned why other firms would be willing to invest in the invention without exclusive rights. For the reaons previously discussed, it does not follow that the taking of title from large firms will lead other firms to invest in the invention. The large firm still has other advantages that would deter such investment. It would seem that the Government would have to do more than merely take title. It would, in turn, in most cases have to grant someone else an exclusive license. But it could be asked what advantage there is to going through the cost and effort of an exclusive licensing effort as opposed to allowing the inventing

contractor, who as required under H.R. 8596 has represented that he intends to work the invention, the exclusive rights.

It would furthermore appear that if, under an H.R. 8596 approach, an inventing contractor obtains title with the real intent not to work the invention, the "march-in" rights left to the Government would be sufficient to remedy such a situation.

Furthermore, without getting too deeply into the even more arcane subject of patent law, per se, we note that just because a firm has a patent does not necessarily guarantee that others will not be able to work the invention. The courts have discretion whether they will grant injunctive as opposed to monetary relief. It is highly unlikely that the courts would grant injunctive relief in the case of inventions that are critical to public health, safety, or other national needs, where the patent owner is not working the invention. Accordingly, even aside from Government "march-in" remedies it is unlikely that a really critical invention could be suppressed by a Government contractor or any other patent owner.

Moreover, for a variety of practical reasons, it would be a mistake to believe that a title-in-the-Government licensing approach could be as effective in promoting utilization as leaving title-in-contractors. As mentioned previously, a title-in-the-Government approach might eliminate the incentive for many grantees and contractors to report inventions. In the case of the university community it is the principal investigator who normally starts the process moving by identifying inventions. Since publication, and not patents, are critical to the careers of university investigators many are not motivated to report inventions. 1/ However, this can be overcome by aggressive programs at the university to induce reporting, especially by an active licensing program that offers some possibility of financial reward for the inventor. Such incentives to the inventor are completely lost when the Government automatically takes title. Within the business sector, a similar decrease in reporting might result, although probably for different reasons.

/ We would remind the reader that about two-thirds of the basic and applied extramural research supported by the Government is performed by universities and other nonprofit institutions. Second, the Government would be faced with an enormous increase in workload. For example, the Defense Department receives some 1500-2500 invention disclosures a year from its contractors. In the great bulk of these the contractor has the right to elect rights. It appears that they do so in about one-third to one-half of the cases and that DOD now examines those inventions in which contractors do not claim rights and file patent applications on perhaps 35-50%. DOD's basis for filing, as we understand it, is the potential application of these inventions to military programs and DOD's desire to guard against future royalty claims on such inventions. They do not analyze these inventions for commercial potential, although it may well be a safe assumption that if a contractor did not request rights that the commercial potential is low. There is, in effect, a screening process performed by DOD's contractors as well as those of other agencies. Under a title-in-the-Government approach this screening would not take place. Thus, under a title-in-the-Government approach DOD would be faced with some 1500-2500 inventions a year on which a decision would have to be made concerning the filing of patents. If DOD continued to base that decision solely on potential military applications, it ought to be obvious that patent applications will not be filed on a number of inventions that have commercial potential but not military potential. Therefore, if one is to honestly argue that a title-in-the-Government approach will not have negative impacts on innovation, one must be prepared to say that DOD and other agencies must screen invention disclosures for commercial application. However, that would require a substantial increase in agency staffs and resources devoted to such tasks. To duplicate the efforts now undertaken by many contractors and a number of universities, the Government agencies would have to be prepared to discuss the inventions with various industrial experts, to run patent searches, and to undertake a substantial amount of sophisticated market and technology analysis that is beyond their normal missions and capabilities. It is unlikely that many agencies would be willing to expand their staffs to undertake such efforts. We think it equally unlikely that the Congress would provide them with the funds necessary to undertake such a program. It is one thing to say that the Government should take title and license inventions, and quite another to obtain the staff and funds to do this effectively.

Third, Government licensing efforts will be hampered by the fact that the Government will not have available to it the expertise and know-how of the inventor and the technical team that conceived the invention. Successful patent licensing often requires transfer of more than a bare right in a patent. Agreements to provide technical assistance may be required which the Government could not offer. Moreover, in the case of many inventions coming from the larger firms, the invention may simply be an improvement on existing technology controlled by the inventing firm. Because of the existence of dominant background patents, the invention will be of no use to anyone but the inventing corporation.

Fourth, it is not always obvious at the time an invention is made that it will ultimately have commercial importance. In many cases, it is the perserverence of the inventor or other technical personnel with the firm who foresee an invention's possibilities that persuades a company to go ahead with development. For example, Battelle Columbus Laboratories did a study to identify the factors which influenced the movement of ten current technologies from their original conception state into actual use. They concluded:

"The technical entrepreneur, whose importance was highlighted in the study of the 'factors', is also a 'characteristic' important in nine of the ten innovations. This is the strongest conclusion that emerges from the study. In fact, in three innovations, the technical entrepreneur persisted in the face of the inhibiting effect of an unfavorable market analysis. If any suggestion were to be made as to what should be done to promote innovation, it would be to find--if one can, technical entrepreneurs." 1/

We believe "technical entrepreneurship" will largely be lost under a title-in-the-Government approach. Accordingly, it is unreasonable to believe that Government licensing would be as effective in promoting the development of contractor inventions as leaving title-in-the-contractor.

1/ Battelle Columbus Laboratories, <u>Science</u>, <u>Technology</u> and <u>Innovation</u>, <u>Summary Report</u> - February 1973, p. 8.

- 11 -

We will next discuss the impact of alternative patent policies in the area of health-related inventions. This provides a clear case study, since one can compare the results of DHEW's pre-1968 title-in-the-Government oriented policy with its experience since that time when a more title-in-the-contractor oriented approach was adopted.

(3) Impact of Patent Policy on the Public Health.

A significant portion of Government R&D is devoted to medical research. DHEW, NSF, the Department of Agriculture and to a lesser extent other agencies such as DOD and the Veterans Administration support extramural research in the medical life sciences. Out of such research new compounds are often synthesized which may have pharmaceutical potential. Experience at NIH and studies by the General Accounting Office 2/ and Harbridge House 3/ clearly support the conclusion that a title-in-the-Government patent policy that did not make an exception for medical research would endanger the public health. However, proponents of a title-in-the-Government approach have never suggested that medical research be excepted from the policy. Indeed, even the President's Statement on Government Patent Policy unfortunately specifically singles out health as an area in which the Government should take title.

The GAO and Harbridge House reports noted above, which were based on extensive interviews with National Institutes of Health grantees and staff, concluded that the pharmaceutical industry would not utilize

1/ Over one-third of the federal R&D budget for basic research in FY 1977 went for the life sciences which include medical and related research. See Report, supra note 1, p. 24. Similarly, one-third of the federal applied research budget was devoted to the life sciences, ibid, p.29. These percentages cover both in-house and extramural research, and the exact percentages of extramural, life science obligations may vary from these figures.

- 2/ GAO Report B-164031 (2), August 12, 1968, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry."
- 3/ Harbridge House, Inc., Government Patent Policy Study for the FCST Committee on Government Patent Policy, May 15, 1968, Vol. II, Parts II and III.

its risk capital to pursue further development of potential pharaceutical agents genrated with DHEW support without a guarantee of some patent exclusivity. With the passage of the Medical Devices Act of 1976, which requires premarket clearance of many medical devices, it is becoming increasingly apparent that the same need for patent protection applies to the medical devise area. In some situations, the GAO discovered investigators with hundreds of compounds with potential therapeutic value on their shelves with no source to test their market potential. The GAO criticized for its failure to use its discretion to enter into Institutional Patent Agreements (which it had not done since 1958) or to make timely determinations of rights after identification of inventions.

Since 1969, when DHEW begain using its discretion as suggested by the GAO, until the fall of 1974, DHEW estimates that the intellectual property rights to 329 innovations made in performance of DHEW-funded research were being managed by institutions with IPA's or by successful nonprofit petitioners for the purpose of soliciting further industrial support. During this period, these organizations have negotiated 44 nonexclusive and 78 exclusive licenses under patent applications filed on the 329 innovations. Since 1974, to the end of fiscal year 1976, the number of inventions held by such organizations has increased to 517. DHEW estimates that the risk capital generated under the licenses on these 517 inventions has been approximately \$150,000,000. 1/

The May 26, 1977, testimony of the Patent Counsel of DHEW, given before the Subcommittee on Science, Research and Technology of the House Committee on Science of Technology includes examples of inventions which have been licensed by universities and nonprofit organizations that have reached or are near reaching the market place. As noted in that testimony most of the examples are pharmaceutical products and medical devices. No comparable examples were known at the time the GAO and Harbridge House ran thier studies.

1/Science Policy Implications of DNA Recombinant Molecule Research. Hearings before the Subcommittee on Science, Research and Technology of the Committee on Science and Technology, U.S. House of Representatives, 95th Cong., 1st Sess. (No. 24), p. 965. It should also be noted that over 60% of the inventions retained by IPA holders or petitioners have not yet been licensed and many will never be licensed or brought to ultimate use. Accordingly, the mere retention of patent rights is clearly no guarantee that commercialization will occur.

(4) The Impact of Patent Policy on Economic Growth and Jobs.

The subject of this subsection is to some extent merely an extension of the discussion in subsection (2) on innovation. In subsection (2) we argued that innovation is better achieved under the H.R. 8596 approach than by the Government taking title to inventions. We have also noted that the innovation process is a prime ingredient in maintaining competition. The purpose of this subsection is primarily to emphasize and explain some aspects of why innovation is essential for economic growth. It should be obvious that without the introduction of new products into the economy, economic growth and job expansion would come to an eventual halt. While people can disagree whether particular technological innovations are good or bad, we doubt that anyone would seriously argue that a slow-down in technological innovation would not result in slower economic growth. Yet, the fraction of R&D performed in this country that is Government supported has now reached around two-thirds. Hence, it is inescapable that a Government patent policy that discouraged investment in the development of the inventions made during that research would have a negative effect on economic growth.

Although we believe the relationship between innovation and long-term economic growth and job expansion are intuitively and historically obvious, several recent studies which are cited below serve to highlight this.

A 1967 Department of Commerce study 1/ and a more recent update of that study by John Flender and Richard Morse of the MIT Development Foundation, Inc. 2/ lend strong support to the proposition that sales growth and job creation occurs more rapidly in innovative companies than in mature (dominant) companies. And even more significant for purposes of this

- 1/ Technological Innovation: Its Environment and Management, U.S. Panel on Invention and Innovation. (Washington, D.C., GPO, 1967).
- 2/ John O. Flender and Richard S. Morse, <u>The Role of New Technical</u> <u>Enterprises in the U.S. Economy</u>, M.I.T. Development Foundation, <u>Inc.</u>, October 1, 1975.

analysis is the fact that job expansion at young (i.e. small) high technology companies was even moire spectacular. 3/ These findings indicate that a patent policy that would deemphasize the needs of smaller firms and emphasize concerns with larger firms could have a negative impact on job expansion.

The potential harm that could accrue from discounting the need to be concerned with inventions from nondominant firms is further emphasized by a study done by Gelman Research Associates. An international panel of experts selected the 500 major innovations that were introduced into the market during 1953-73 in the U.S., U.K., Japan, W. Ger., France, or Canada. Of the 319 innovations produced by U.S. industries, 24% were produced by companies with less than 100 employees. Another 24% were introduced by companies with 100 to 999 employees.

Therefore, to the extent we are correct in asserting, as we did in subsection (2) that the H.R. 8596 approach is much more likely than a title-in-the-Government approach to bring about innovation, it is indisputable that the H.R. 8596 approach is also much more likely to encourage economic growth and job expansion.

(5) The Impact of Government Patent Policy on Foreign Competition.

Our discussion in subsection (1) of the effect of Government patent policy on competition alluded to the fact that title-in-the-Government advocates may have reached their conclusions through the use of a static rather than a dynamic model of competition. We think their analysis also almost totally ignores the fact that the U.S. economy does not operate in a vacuum. American industry is in increasing competition with foreign corporations in high-technology areas. But a title-in-the-Government patent policy must inevitably work to the advantage of foreign firms at the expense of American industry and labor.

^{3/} The authors found that during the 5 year period of 1969-70 "six mature companies with combined sales of \$36 billion in 1974 experienced a net gain of only 25,000 jobs, whereas the five young, high technology companies with combined sales of only \$857 million had a net increase in employment of 35,000 jobs.

The taking of title by the Government will effectively prevent the American inventing corporation from obtaining foreign patent protection. And without Government foreign filings no American firm could gain any exclusive rights in foreign markets. But historically the Government agencies have had neither the incentive, the staff. the budget, nor sufficient knowledge of market conditions to file for foreign patents in anything more than a small number of cases. 1/

Secondly, if the Government takes title to U.S. rights in inventions and dedicates them, these inventions are equally available to foreign based firms that would export commercial embodiments of these inventions into the U.S.

If you combine these facts with the difference in the relationship between business and Government in certain foreign countries as compared to relations in the U.S., certain disturbing implications arise. In some foreign countries industry is highly socialistic and state controlled. In others, major companies may enjoy state subsidies and support. The result of all this is that the same invention that U.S. firms may not develop without the exclusivity afforded by patent rights may be developed by Japanese, Germany, or other foreign firms that enjoy monopoly advantages in their home markets through means quite apart from patents. In turn these products are exported into the United States and displace American products and American jobs.

In short, given the difference in industry-Government relations in many of the technologically advanced foreign countries as compared to the United States, a title-in-the-Government policy is most likely to favor foreign companies. We would emphasize that we in no way mean to imply that the United States should abandon its antitrust policies. Instead, we believe that the existence of the antitrust remedies makes it extremely foolish for the United States Government to fashion its patent policy primarily on hypothetical and we believe mistaken concerns about the impact that policy will have on competition within the United States while ignoring the many adverse effects that a title-in-the-Government policy would have. If, in a few isolated cases leaving title with Government contraactors is found to be a contributing factor to a course of conduct or a monopolistic position that is in violation of the antitrust laws, then the Government should seek to remedy such abuses through antitrust laws.

1/ Statistics by the Committee on Government Patent Policy show that during the period of FY 1970-75 the Government filed for foreign patents on an average of 77 contractor inventions, and the preponderance of these were by only two agencies, DOE and NASA. This is approximately one-tenth the number of contractor inventions upon which the Government filed U.S. patent applications. The existence of the antitrust remedy would seem to lessen the need to be concerned over occasional anticompetitive situations that theoretically might emerge from a title-in-the-contractor policy.

(6) The Impact of Government Patent Policy on Contractor Participation.

The issue of whether Government patent policy affects the willingness of potential contractors to participate in Government R&D efforts is again tied in, to some extent, with the arguments in the previous subsections. However, it also constitutes a separate subject and does represent an important impact of Government patent policy. Apparently, this consideration has been the primary one that has influenced the Defense Department to adopt a title-in-thecontractor oriented policy.

Because of obvious detrimental effect a title-in-the-Government patent policy could have on the national defense effort if, indeed, such a policy would have negative impacts on contractor participation, title-in-the-Government advocates have generally gone to great efforts in their presentations to discount this possibility. They often claim that there is no evidence to support the contention that taking title will deter firms from participation. They will also enumerate various advantages to taking Government contracts which they claim will lead firms to accept Government work regardless of the patent terms. 1/

1/ Assistant Attorney General Shenefield made the following statement in his testimony of December 20, 1977, to the Select Committee on Small Business, U.S. Senate: "We are not aware of any convincing showing that exclusive rights in government-financed inventions need be granted to contractors in order to induce them to accept government R&D contracts, which themselves confer many benefits beyond the simple contract price. Among these benefits are the opportunity to traing key personnel, expand research facilities, develop know-how-all with government aid--and apply these assets to further the contractors' own commercial objectives. These contractors may also receive government data and know-how inaccessible to their competitors. As a result, contractors participating in government-funded research programs can acquire a long and significant lead over their actual or potential competitors.

See, also, the testimony of Admiral Rickover before the same committee on Decmeber 19, 1977.

No one denies that in many instances a firm will accept Government work regardless of the patent terms, often for the reasons given by title-in-the-Government advocates. However, there is ample evidence that there are cases when patent provisions will affect the willingness of firms to accept Government research grants or contracts. The DHEW experience with the pharmaceutical industry in connection with its cancer chemotharapy drug research program in the 1950's is a clear cut example of firms refusing to participate in Government programs without patent rights.1/ Harbridge House, in its 1968 study of Government patent policy, concluded that there were a number of situations in which a title-in-the-Government approach would affect contractor participation. They, of course, also noted that in many cases it would make no difference. We believe numerous Government procurement officers and attorney's could provide anecdotal evidence of instances in which particular contracts would not have been consumated if the Government had insisted on obtaining rights to inventions. In short, the arguments of the title-in-the-Government advocates concerning contractor participation contradict actual experience.

As is discussed later in Section (2), many universities have found that concern over Government patent policy often deters private industry from supporting university research in areas where related Government work is being performed. It seems obvious that those same concerns would affect a firm's willingness to do work for the Government that parallels its private research efforts. While undoubtedly DOD would have little trouble getting prime contractors for major systems development contracts regardless of patent terms, the same could not be said of many potential subcontractors under those contracts. It should not be lost sight of that while a major weapons system may not have a commercial counterpart, many of its subsystems or components have commercial markets or are improved versions, with perhaps higher performance characteristics, of commercial items. Their commercial equivalents may be proprietary or covered by patents. We believe that it would be naive to believe that if the Defense Department attempted to flowdown a title-in-the-Government clause through the numerous tiers of its subcontractors that major problems would not emerge.

1/In 1958, the Public Heath Service was forced to amend its regulations to allow commercial concerns to retain rights to inventions made under contracts under this program in order to get the pharaceutical industry to accept contracts.

- 18 -

The effects of the refusal of certain potential contractors to participate in particular contracts or subcontracts would seem to be the following:

1. Procurement costs might increase in cases where firms with proprietary interests refused to participate since the actual contractors would probably have to duplicate much of the research already performed by the more advanced nonparticipants.

2. The quality of the final product might be lower, a perhaps unacceptable risk in the arena of military procurement.

3. Government procurement might become increasingly concentrated in larger, more dominant firms. That is, it would seem to us that large, dominant firms would be more willing to accept Government awards even without guarantees of patent rights than will small and mid-sized firms that have more need for these rights to protect and improve their position. As a result more and more Government work, at the prime and subcontractor levels will be performed by fewer and fewer firms.

In summary, there is absolutely no question that a title-in-the-Government policy would have an adverse affect on contractor participation. The only real unknown is the precise parameters of the problems in this area that such a policy would create.

(7) The Cost of Administering Alternative Patent Policies.

Somewhat related to the contractor participation issue is that of the administrative costs and burdens entailed by alternative policies. It should be obvious that the H.R. 8596 approach would minimize administrative costs or burdens, since negotiations with contractors and processing of waiver requests would be unnecessary. Similarly, if the Government adopted a hard and fast, take it or leave it, title-in-the-Government policy, these costs would also be minimized. However, assuming such a policy was combined with an active Government licensing program, the administrative costs would be much higher than an H.R. 8596 type policy. (See our earlier discussion in subsection (2) on innovation.) It seems fairly obvious, however, that a complete take it or leave it title-in-the-Government policy is not possible. The result will be requests by numerous potential contractors and subcontractors for more liberal terms. Many of these requests will have to be considered if Government programs are to proceed on a timely basis. Thus, it seems clear that the taxpayer will pay more for the administration of a title-inthe-Government patent policy than they will for the administration of an H.R. 8596 approach.

A Comparison of the H.R. 8596 Approach with the Case-by-Case Approach.

Our preceding discussion has been limited to a comparison of the H.R. 8596 approach with a title-in-the-Government approach to Government patent policy. We think that discussion and analysis leads to the conclusion that a titlein-the-Government approach is a totally unrealistic way of formulating a uniform Government patent policy. Conversely, the H.R. 8596 approach is a feasible one which would promote the various objectives that can be influenced by Government patent policy. The question remains whether a case-by-case approach would be superior or inferior to an H.R. 8596 approach. This section is devoted to this question, and we will again consider the different impacts of the two policies in each of the seven areas discussed previously. Our conclusion is that the H.R. 8596 approach is superior to a case-by-case approach.

We would remind the reader, as stated at the beginning of this paper, that the case-by-case approach can encompass a number of variations. It might, as is currently normally the case, assume that agencies would select in individual cases among title-in-the-Government, title-in-the-contractor, or deferred determination clauses. Or it could assume that only deferred determination clauses would be used. Depending on how the policy is stated, it might have a presumption in favor of title-in-the-Government or titlein-the-contractor. It might or might not be accompanied by the assumption that the Government would undertake to license inventions to which it obtained title. Where these differences are relevant to our analysis, we attempt to account for them.

One point we would also emphasize is that one who advocates a case-by-case approach presumably should have the specific variation which he would choose in mind. We would make the observation that while the choice of one specific variation may help to mitigate what we might argue are the adverse effects of a case-by-case policy on a specific objective, it may well turn out to compound the problem with respect to another objective. In short, we caution that it is not appropriate to shift from variation to variation depending on the objective that is being discussed.

(1) Administrative Costs. A case-by-case approach would be substantially more costly to administer than the H.R. 8596 approach. Agencies might have to establish an internal process to decide which clause to place in each grant or contract. It can be expected that in numerous cases where other than a title-in-the-contractor clause is proposed negotiations will have to be undertaken. The agencies may even find themselves forced to negotiate subcontract provisions even in cases where the prime contractor is willing to accept a title-in-the-Government or deferred determination clause. The Government will also have to process numerous requests for deferred determinations that would not have had to be processed if the contractor had been allowed rights at the time of contracting. Finally, depending on which variation of the case-by-case approach was adopted, a Government licensing program might be required.

(2) Contractor Participation. It should be obvious that a case-bycase approach, at best, could only equal the H.R. 8596 approach in terms of its impact on contractor participation. That is, the contractor participation problem occurs in situations where contractors are not guaranteed rights at the time of contracting. The use of deferred determination clauses does not overcome this problem. The contractor participation problem could only be successfully alleviated under a case-bycase approach if the Government used a title-in-the-contractor clause in each instance when contractor participation was a problem. However, there is no way the Government could identify such situations in advance, and the Government would certainly find it difficult to determine just which firms were bluffing and which were not. Moreover, if the solicitation went out with a title-in-the-Government or deferred determination clause, some firms might simply refuse to bid knowing that they would have to go through a hassle over patent rights. Hence, we believe that H.R. 8596 is clearly superior to a case-by-case approach in avoiding contractor participation problems.

(3) Foreign Competition.

The problem of foreign competition cannot be dealt with under a case-bycase approach to Government patent policy. This is because while one can predict that in some cases if the Government takes title to inventions and makes them freely available foreign corporations will benefit, one cannot identify, in advance, in which cases this effect will occur. There appears to be no rational way in which Government decision makers could be expected to have sufficient facts and understanding to predict that if they kept title to a given invention that a foreign corporation would exploit the invention while American firms would not.

As an analogy, one could predict with reasonable certainty based on past experience the approximate number of Americans who will die from accidental causes in the course of the next year. But there is no way of identifying the specific individuals who will suffer this fate.

Only by allowing contractors the right to normally retain title can we feel any confidence that our patent policies will maximize, to the extent they can, the position of U.S. industry in the world markets.

(4) Public Health.

As discussed earlier severe utilizations problems emerged in the public health area when contractors were not guaranteed exclusive rights. And in cases where the R&D needs to be performed by commercial concerns, obviously the use of deferred determination provisions would not eliminate participation problems, since the contractors will want guaranteed rights. 1/ A case-by-case approach would, therefore, in order to operate as satisfactorily as the H.R. 8596 approach

1/ See fn. 1, p.18.

have to operate with a heavy bias in favor of leaving title with the contractor. In essence, a case-by-case approach would have to operate as a title-in-the-Contractor approach as it applied to medical and related research if it was not to have detrimental impact on the public health. We thus see no advantage in adopting a case-by-case approach as opposed to the H.R. 8596 approach vis-a-vis public health concerns. Indeed, unless truly liberally administered, the result would be most likely to be detrimental to the public health.

(5) and (6) Economic Growth and Innovation.

For purposes of this discussion we are combining the two factors of economic growth and innovation since as our previous analysis indicated the economic growth objective is basically a function of the rate of innovation. However, in line with our attempt to consider separately each of the objectives of patent policy we remind the reader that the following discussion attempts to isolate the innovation objective from the competition objective. 1/ In the final subsection we will examine in more detail the competition objective.

We think all parties can agree that patent policy should be designed to stimulate the development of inventions into new products and processes. The basic disagreement is over how this is best done. We think it is fair to state the supporters of H.R. 8596 would agree that in some cases innovation will take place just as quickly even if an inventing contractor is not allowed to retain rights. On the other hand, most title-in-thegovernment advocates recognize that there are cases when innovation will be fostered by leaving title in a contractor. However, these same advocates would also argue that in some cases innovation will be more likely to take place if the Government retains title and in some cases dedicates or in others licenses the invention. And one would have to concede that in some cases this might well be true. The argument goes, therefore, that the best thing to do is for the Government to decide each case individually in light of the facts.

There are unfortunately certain problems that make this seemingly ideal and rational approach unworkable. To put the matter simply we find it difficult to believe that Government agencies would have sufficient staffs, budgets, and expertise to undertake the rather detailed technical, economic, and marketing studies that would allow anyone any degree of confidence in

1/ See introduction to subsection (2) on p.6, supra.

his prediction that taking title from contractors would improve the chances of innovation. Also, we think the same problem of identifying individual cases discussed in the foreign competition section may be at work here.

The experience of most persons involved in technology transfer is that the chances of a given invention being commercialized are considerably enhanced if exclusivity is available. We would remind the reader of the 1968 Harbridge House findings discussed earlier at page 8.

We believe that a case-by-case approach would not increase the chances of innovation. Presumably innovation would only decrease in cases where a contractor retained title and failed to use the patent and prevented others from doing so. We fail to understand how the Government could predict such behavior either at the time of contracting or after an invention was identified. It seems to us that the Government's march-in rights are the real remedy for such behavior.

The only other variation that might be suggested would be for the Government to defer a decision until it announced the existence of the invention and accepted offers, i.e. it established a licensing program. While in theory such a solution may be attractive in reality it is unworkable and has severe drawbacks which were discussed previously. We do not know why the Government should be any more successful than universities in finding nonexclusive licensees. If the Government, therefore, offers an exclusive license, we wonder how the Government could be any more confident that its exclusive licensee will develop the invention more quickly than an inventing contractor who makes the representation required under H.R. 8596. And if the Government grants nonexclusive licenses, as they will be under strong pressure to do, how do Government officers know that dominant firms will not offer to accept such licenses simply to prevent a potential competitor from obtaining an exclusive license. Tn point of fact, one is likely to find that only the large companies will have the staff to keep track of inventions being offered for license by the Government.

Moreover, an discussed previously, a policy in which rights are not guaranteed to contractors at the outset could have the effect of decreasing the number of inventions reported to the Government. We believe many university investigators would soon learn that there is no particular advantage to reporting and identifying inventions since about all they will get out of this is the "honor" of having to help Government attorneys prepare patent applications. Similarly a complicated and time consuming deferred determination procedure is likely to discourage many universities from requesting rights. We suspect that under a case-by-case system the Government will be so busy making determinations in those cases where contractors and grantees are not discouraged from requesting rights that the Government will have no resources left to do anything with invention disclosures which are not accompanied by requests for rights. We think a similar phenomenon would occur with some of the Governments profit-making contracators and subcontractors. There is a possibility that some contractors may decide it is more in their interest to refrain from disclosing inventions, and they may not report inventions in which they can make a reasonable case that the invention was outside the scope of the contract. Without voluntary disclosure, as a practical matter we think it unlikely that the Government or others would be able to recognize that particular patented products should be subject to royalty-free Government licenses and march-in rights. Only through happenstance and expensive litigation is the Government likely to discover and establish its rights for whatever worth that may prove to be.

Again, we are not denying that there might be a few cases under a deferred determination approach in which denying a contractor rights will result in earlier innovation than would have been the case if the contractor had obtained rights under the H.R. 8596 approach. We do not believe that such cases will occur often enough, however, to overcome the other problems cited above. In addition, one must also expect that in some cases the Government will come to the wrong conclusion and deny contractors rights in cases in which, if the truth were only known and the future predictable, it would be found that this denial stymied the further development of the invention.

In summary, given the overwhelming evidence that innovation is fostered by exclusivity, only with 20-20 hindsight could the Government be expected to improve the odds in favor of innovation that leaving rights to contractors provides. And, even if the Government had some magical means of always reaching the proper determination, the time consuming and expensive process would likely have a negative effect on the total number of inventions reported and the willingness of some inventing organizations to pursue rights.

Thus, we seem to be back where we were during our comparison of the H.R. 8596 and title-in-the-Government approaches. That is, for each of the six objectives discussed so far, we find the H.R 8596 approach superior to a case-by-case approach. Thus the case for an approach other than H.R. 8596 once more depends on the competition objective, and further assumes that this objective is overriding.

(7) Competition.

We concluded in our earlier comparison of title-in-the-Government versus the H.R. 8596 approach, that the latter would really promote competition more adequately than the former. The question that must be examined now is whether a case-by-case approach will do an even better job by ensuring the use of the best approach in each individual case. We believe a reasonable way to approach this is to examine the types of situations in which leaving title in contractors might prove anticompetitive and then to examine whether it would be reasonable to expect that the Government could prevent this by a caseby-case examination. This discussion will concentrate on situations where the inventing contractor is a large, dominant firm or one that controls a substantial share of its commercial markets. We assume that title-in-the-Government advocates do not consider it anticompetitive for a smaller competitor to develop an invention into a product that allows it to increase its share of the market. Presumably, that increases competition.

Leaving an invention with a dominant firm could arguably lead to an anticompetitive result in certain situations. One situation would be where the firm chooses to suppress the invention and not use it or license others. For reasons discussed previously, we do not understand how the Government could rationally predict such behavior. Again, marchin rights appear to be the only answer to this.

A second anticompetitive effect might be that the large firm would develop the invention so as to further enhance its dominance. However, for the various reasons discussed previously, it can be doubted that very many of these inventions would actually be used by competitors even if they were freely available to them on a nonexclusive basis. There is, of course, little doubt that there would be cases when they would use them. One can certainly hypothesize sets of conditions, which will sometimes occur, which would support this. However, again, while such cases may be identifiable with hindsight, as a practical matter it seems highly unlikely that Government personnel could identify these situations in advance. Because Government personnel will lack the detailed knowledge of market conditions, the various firms involved, the technology involved, and alternative technologies that would be required to exercise a meaningful judgment, it can be expected that case-by-case decisions will be decided on the predilections of individual decision makers. And we will not relist all the other problems that such a costly and elongated process would entail. The impossibility of a truly meaningful case-by-case process suggests to us that the Government would be better advised to establish a policy that takes advantage of the fact that in most cases the H.R. 8596 approach seems destined to prove beneficial.

One might argue that this problem could be avoided if under a case-bycase approach, the Government took title to the inventions of dominant firms and used a licensing program. Under this approach, one could argue one could come out ahead if you ended up giving an exclusive license to a small firm. We will not reiterate the various problems and drawbacks to Government licensing that we have previously discussed. We would, however, note that the same persons who advocate title-in-the-Government oriented policies, also seem to oppose the granting of exclusive licenses by the Government except as a last resort.

Another observation that needs to be made, and one that may pertain to any suggestion that under a case-by-case approach the Government could distinguish between its treatment of dominant and nondominant firms is this. How could procurement officials and program officers determine which firms are "dominant"? A good part of antitrust law seems devoted simply to determining what is the relevant market in any given case. The resolution of this issue, on an after-the-fact basis, during the course of antitrust litigation may take years and require detailed analysis by economists and others. At the time of contracting how could one possibly even know the commercial markets to which would-be inventions might pertain. And even after an invention is identified this may be an equally impossible question since the invention may have multiple potential uses. And even where its use is tied closely into an ongoing product line, one is back to the problem of identifying the relevant market. The administrative nightmare that would be created ought to be readily apparent.

In summary, it is highly dubious whether a case-by-case approach would increase the competition generated out of given inventions. We admit that in some cases it might. However, we remind the reader that in line with the discussion in the preceding subsection, even if the result were beneficial vis-a-vis some inventions, innovation will be decreased. With fewer innovations long-term competition under a dynamic model of the economy would decrease.

We would also note that competition is desirable presumably because it results in lower prices to the consumer. Since the administrative costs of a case-by-case approach that was truly designed to attempt to fully access the facts in each case would be enormous, these costs must be weighted against potential price decreases. Since in our estimation the number of cases in which a case-by-case approach is likely to increase competition and possibly lower prices as compared to the H.R. 8596 approach will be miniscule, these savings are highly unlikely to offset the higher administrative costs that would have to be borne by the taxpayers year after year.

Finally, one more fact that we believe needs to be weighted in the overbalance is that even if in a few cases higher prices resulted from a contractor retaining title, the consumers nevertheless must find the product a better value than its prior alternatives or they would not pay the price.

Summary

We believe it apparent that careful examination of the impact of alternative patent policies on the various objectives of Government patent policy shows the H.R. 8596 approach to be superior to any of the alternatives on every count. No doubt title-in-the-Government advocates would reject our analysis of the competition situation, but it is doubtful that they will be prepared to provide any reasonable analysis to support their rejection. In any case, it is unclear why the competition factor should be deemed to outweigh the other factors we have enumerated.

While with hindsight one could probably show that in some situations the various objectives on balance would best have been served by the Government keeping title, it seems clear that all evidence points to this being the case in only a small percentage of situations, some of which, in any case, can be accounted for by the discretion left in agencies under H.R. 8596 to deviate from the standard provisions. More importantly, while 20-20 hindsight may reveal individual situations in which it would have been better for the Government to have obtained title, our analysis has shown the practical impossibility of reasonably identifying such cases in advance. If one examines carefully the various solutions that title-in-the-Government advocates often proffer to mitigate the concerns of advocates of the H.R. 8596 approach, one will find that they presuppose an ability in Government officials to predict a future course of behavior that could only reasonably be predicted if one possessed a wealth of knowledge about specific technologies, industries, firm capabilities, and other factors that is just not available. And even to gain a fraction of the knowledge that would make the decision-making process anything more than a ritualistic affirmation of the decision-maker's predilections would require such an enormous administrative cost as to probably offset any hypothetical savings to consumers that might be generated by the increased competition that is supposedly going to result from the process.

We, of course, do not claim that patent policy is necessarily the dominant force in shaping any of the objectives. Overall other factors will have a much greater influence on competition, innovation, and economic growth than will Government patent policy. We do believe, however, that patent policy will have a definite influence, for better or worse, depending on the policy, in each of the areas we have discussed. While one cannot, unfortunately, measure with any precision the exact magnitude of the impact in any of the areas (save, perhaps, administrative costs, if one defined precisely how each policy was to operate), we feel it would be foolish to ignore the obvious direction in which patent policy can affect these objectives. The weight of experience and evidence strongly suggests that H.R. 8596 represents the proper approach to Government patent policy. There is virtually no reason to suppose that either a title-in-the-Government or case-by-case approach would prove as beneficial.

Section 2. <u>Considerations Affecting Government Patent Policy as it Pertains</u> Specifically to Universities.

The university community is concerned with Government patent policy not only for the general reasons set forth in Section 1, but also because of the impact these policies can have on university operations.

Many universities believe they have an obligation as public institutions to attempt to transform the ideas and knowledge developed at the university into useful products and processes. The universities also believe that the licensing of their inventions is a potential source of income to support further research and educational activities. Without attempting to draw the line between where one motive starts and the other ends the clear fact of the matter is that unless a university is allowed to retain rights in its inventions in the great majority of cases private industry will not invest in the commercialization of these inventions and most universities would have little incentive to devote staff and resources towards interesting industry in pursuing the development of inventions. Our previous discussion has outlined some of the reasons for this. And the reasons for this are well developed in the 1975 Report of the Ad Hoc Subcommittee on University Patent Policy, Committee on Government Patent Policy, FCST. Likewise, we think that report accurately describes the shortcomings of alternative approaches. In the interest of brevity, we would refer you to that report rather than repeat the various points it made. The university community agrees with the analysis in that report which was prepared by various experts within the Government.

Government patent policy can also have a very signifcant impact on efforts to obtain industrial support for university research. Quite apart from the licensing of inventions, the university community is vitally interested in expanding the contributions of industry to university research.

However, it has been the experience of the universities that many companies that might otherwise be interested in supporting research will decline to do so if it is found that the university investigator is carrying on related work under Government sponsorship in which the Government controls the disposition of any inventions. While many firms do not demand the assignment of future inventions as a condition of support, many at a minimum, want some sort of right of first refusal for a license. If a company believes that the university rights will be confused and uncertain because of the related Government work, typically it will back off and support will not be obtained. On the other hand, if the Government related work is being done for an agency such as DHEW or NSF with which the university has an Institutional Patent Agreement allowing it to retain rights, most companies are satisfied and will consumate an agreement to support university research in which they are interested. Thus, it should be well understood that because such a large percentage of university research is Government-sponsored, unless Government patent policies provide for certainty of rights in the university, it will be extremely difficult to achieve anywhere near total amount of industry support for university research that would seem potentially achievable.

Finally, we believe that a title-in-the-Government policy completely ignores the equities of the university community in inventions made by university investigators. Rarely does the Government pay full salary of university investigators. Overhead costs are shared by the university. The facilities and libraries in which research is performed has usually been payed for in whole or in part through private sources or State financing. The universities, many of which are state supported, are as responsible, perhaps more so, than the Government for establishing the environment in which inventions are made. For the Government to take title to university inventions is to ignore the equity of the universities and the States that support them. We see no reason to believe that universities, as public institutions, are not as capable as the Government of obtaining utilization of these inventions in a manner designed to protect the public interest. Indeed, it is obvious if one compares the university record with that of the Government that we are much more capable of securing private investment in the further development of our inventions than is the Government.

Section 3. Problems with the "Status Quo".

The previous analysis has explained the reasons why the university community believes H.R. 8596 represents the optimum approach to Government patent policy. We were, however, also asked to provide comments on what, if any, problems we might foresee if, instead of the enactment of H.R. 8596 the "status quo" were maintained.

There are two classes of reasons why that suggestion disturbs the university community. First, the current "status quo" is essentially a mixture of title-in-the-Government oriented piecemeal legislation and/or the case-by-case approach as represented by the President's Memorandum and Statement of Government Patent Policy. Since our previous analysis has shown these approaches to be inferior to the H.R. 8596 approach, it seems desirable to change the situation. In President Carter's words, "Why not the best?" Secondly, and perhaps more importantly, it seems inevitable that without the enactment of legislation along the lines of H.R. 8596, Government patent policy will move further and further in the direction of a title-in-the-Government oriented policy through the enactment of further piecemeal legislation and because of changes in key administrative personnel.

On the first point, two major R&D agencies, NASA and DOE, are essentially forced by their statutes to use a deferped determination approach. A number of other agencies also have interpreted various enabling statutes to require a title-in-the-Government or deferred determination approach with respect to all or signifcant portions of their R&D®activities. These include the Department of Agriculture and Interior, and there are others. Obviously, if one concludes that H.R. 8596 embodies the proper approach to Government patent policy, one should not be satisfied to have significant portions of Government R&D activities governed by counter-productive legislation.

We also believe that the President's Statement on Government Patent Policy, which is the other major document governing current policies, is somewhat overbalanced in the direction of title-in-the-Government. For example, we see little justification for section l(a)(ii) which establishes a rule that the Government should take title to inventions resulting from health-related research. As discussed previously the experience of DHEW clearly demonstrates the folly in having drugs and other health-related inventions placed in the public domain. We also believe that while section 1(a)(i) may be partially correct, much depends on how this section is interpreted. We would agree that if the Government awards a contract to develop and carry a product all the way to the commercial market place that the Government should retain control over the disposition of inventions made under the contract. However, it is relatively rare for the Government to fund items that far, yet it seems unclear whether section 1(a)(1) is meant to apply where the contract is to support some development, but only at a relatively early stage, and where considerable private investment will still obviously be needed to bring any product to the market.

Secondly, we judge the current "status quo" to be a rather precarious one, and one that leaves the actual policies and practices of individual agencies subject to arbitrary changes depending on the whims of particular strategically placed individuals. There has been a history both before and since the promulgation of the President's Policy of the Congress inserting title-in-the-Government oriented patent provisions in major R&D legislation, often at the eleventh hour. The NASA Act is a well-known example of that. And more recently, the ERDA legislation was accompanied by restrictive patent provisions. Indeed, it appears that this legislation is even being interpreted to put the universities at a disadvantage as compared to industry in obtaining waivers from DOE. It appears to the university community that the ERDA provisions are likely to become the model used in future efforts to insert patent provisions in legislation establishing or reorganizing R&D programs. Such piecemeal efforts are difficult to prevent because they do not affect all the agencies. Moreover, in the case of new programs there is often no one with an interest in the program who can effectively point out the problems that will be created. And, quite honestly, neither the universities, industry, or persons within the Government who might be opposed to such developments have the time and energy to constantly refight this battle.

It is our understanding that the concern about piecemeal legislation was one of the major factors that led the Committee on Government Patent Policy to prepare a draft bill in 1976. We think it is a very real concern. We do not see how more piecemeal legislation can realistically be prevented unless the attempt is made through the mechanism of H.R. 8596 to get a Government-wide policy adopted. While the passage of H.R. 8596 would not preclude persons from attempting to get piecemeal provisions adopted, its passage would make it considerably easier to combat such attempts and would probably deter them. Indeed, we believe that even if H.R.8596 ultimately fails to secure passage, a vigorous Executive Branch effort to obtain its passage would have beneficial effects. We feel certain that such an effort might at least educate some Congressmen of the issues and facts. Based on this, some of those Congressmen might prove willing in the future to help combat piecemeal efforts to insert title-inthe-Government provisions in R&D legislation.

It is fairly obvious to the university community that under the present circumstances many Executive Branch officials who might otherwise be inclined to move their agencies closer to an H.R. 8596 approach are afraid to do so because of concern over Congressional reaction. Many Federal officials are simply not willing to risk the reaction of certain Senators or Representatives that actively and vocally support a title-in-the-Government approach. Indeed, it would appear to the university community that the timidity with which the Administration has handled the development of its position on H.R. 8596 may reflect these very fears. We note that the Committee on Government Patent Policy recommended a bill substantially like H.R. 8596 late in 1976. Yet, despite the overwhelming support of the Government's experts in this area, higher Government policymakers appear hesitant to actively recommend that the President support H.R. 8596. It seems obvious that without the passage of H.R. 8596, the political climate will be such that it will simply be impossible for the Executive Branch to formulate an effective Governmentwide patent policy.

Related to the preceding observation, the university community is concerned that even those agencies whose patent policies are not governed by restrictive legislation and that have adopted patent policies which are now responsive to the needs of the university community cannot necessarily be counted upon to always follow such policies. For example, the university community generally believes that DHEW, NSF, and DOD, among the agencies not governed by restrictive statutes have had the most responsive university patent policies. Yet in 1976, DOD suddenly abolished their list of universities with approved patent policies and, while we are hopeful that DOD will adopt the Institutional Patent Agreement approach after the Federal Procurement Regulation revisions in this area are issued, there is now a degree of confusion regarding DOD patent policy as it pertains to universities.

We would also note that neither DHEW nor NSF have always had patent policies and practices that were responsive or fully effective. While numerous persons within both of those agencies have been supportive of their current IPA and waiver policies, it is also fairly apparent that without the perserverance, dedication, and understanding of a few key individuals these agencies would not have the policies they have today. Similiarly, it took initiative and leadership from within the bureaucracy to obtain the preperation and adoption of the Report of the Ad Hoc Subcommittee on University Patent Policy by the Committee on Government Patent Policy in 1975, and its implementation in the Federal Procurement Regulations. But we cannot be sanguine that such leadership and initiative will always be present within the Federal bureaucracy. Changes in personnel or in agency leadership may lead to reversals of policy that are not based on a complete understanding of the situation. Accordingly, we would prefer that Government patent policy, assuming it is soundly established, be established by law and not by men.

Finally, a decision to maintain the "status quo" would seem in conflict with the declaration of Congress in the National Science and Technology Policy, Organization, and Priorities Act of 1976 that:

"Federal patent policies should be developed, based on uniform principles, which have as their objective the preservation of incentives for technology innovation and the application of procedures that will continue to assure the full use of beneficial technology to serve the public."

Thus, we urge the Administation to support H.R. 8596 as the means of fullfilling this Congressional declaration.