volve the rights to the discoveries as they may be developed, and any patents that may result—the exclusive rights—as I understand it.

Mr. HOLST. I am saying something which resembles that, Mr. Chairman, but not——

Senator MCCLELLAN. I did pretty well to get close to it. Go ahead and explain it.

Mr. HOLST. You always do extremely well, Mr. Chairman. What I am saying is that if the patent policies actually are such as to threaten the commercial existence of desirable organizations, they will not bid on work which exposes them to that risk.

Senator MCCLELLAN. All right, they won't bid on it. I am trying to understand how the company, the contractor, can possibly be injured or lose something he already has, that he has developed that, say, is superior or very desirable in his particular field. How does he lose that, or how is that in any way impaired, by reason of the contract, if a further development is made by the contractor in the course of work for the Government which the Government may take as its own?

How does that hurt the original contractor? Does it impair the value of what he has already achieved by the investment of his own money and skill that he has applied to it?

Mr. HOLST. Let me give as a kind of an example an illustration which will also serve to form a basis for one of the suggestions I am going to make for a minor modification in your bill.

Let us say that there is a need for a new device, an underwater detection system to spot submarines, and let us say that such an organization as—well, I had better not mention it—but a fine and outstanding organization in the field of acoustics, because it is already working in this field, has both developed and already patented concepts to which it owns the background rights. I have not suggested that those are at the moment in danger. But it also has a number of other ideas partially developed, but not within the language of the bill, at the moment fully reduced to practice.

Senator MCCLELLAN. Not yet patented.

Senator McCLELLAN. In other words, they come primarily with a proposal to do research and development?

Mr. HOLST. Yes.

Senator McCLELLAN. They get some idea and come to the Government and say "This is something you probably need. If you do, we would like to have a contract to further the work we have done and try to bring it into fruition." Is that correct?

Mr. HOLST. That is correct. Sometimes what is offered represents a very substantial effort on the part of the organization. Sometimes it is derived very intimately from the regular activities of the organization which can be applied to meet a governmental purpose. It seems to us that this is a kind of circumstance which the Department of Defense has previously recognized as entitling the contractor to retain commercial rights and which might well be given such consideration under your bill.

Senator McCLELLAN. If a company, in pursuit of its own business affairs, aside from a Government contract, in the pursuit of its commercial business production and sales, has done research to the point where it has developed a pretty good idea, and is fairly well convinced that it can be perfected, so to speak, to make it feasible and workable, and knowing that the Government is in need of such an instrumentality or device, the patriotic thing for it to do probably would be to go to the Government and make such a suggestion; that is, to make the unsolicited proposal that you speak of.

If, however, by reason of Government policy it knows that if it does make such a proposal and it is accepted, that it will lose in a sense the investment it has already made, the labor it has already put into the product to bring it to a point of a great potential, so to speak, then your position is that it would hesitate to go to the Government and offer the unsolicited proposal. Instead it would probably struggle along for another period of time, hoping to finally develop it on its own, although it might take longer?

Mr. HOLST. Thereby delaying the bringing of valuable suggestions to the Government.

Mr. HOLST. I inject the other question, "How best to serve the public interest" because it would seem a shame if the property rights provision should conflict with public interest and I agree entirely with what you have said, that if a contractor carries the develoment through to completion on his own, nothing has been proposed that would deny him the ownership right. But it would seem a shame if it is necessary to sacrifice national interest in early use of developments desirable for defense, health, or other purposes, in order not to conflict with ownership rights, when in fact some other policy would adequately protect both the Government and the public.

Senator MCCLELLAN. Don't misunderstand me by anything I have said.

Mr. HOLST. No.

Senator MCCLELLAN. I don't contend that the Government has no rights. It would have a property right, too, I think, if it goes in there and finances and helps to develop a contractor's conception. But I say there is somewhere an equity, a middle ground, that should accommodate both fairly and justly, and at the same time protect the public's interest and enhance the welfare of the Government's purposes.

Mr. HOLST. I agree with that.

We have been discussing what we think should be one of the special circumstances that have to be given special consideration. I would now like to mention another point which it would appear is not self-evident, and this is the question of the Government's taking of foreign rights and the Government's granting of foreign licenses. It may well be that what I am about to say is not self-evident.

The U.S. Government, in good faith, has a number of treaties with allied governments by which on what appears to be a bilateral basis, each nation has agreed to make available to the other nation any defense-related developments which could be useful to the other. The fact is that this has turned out to be a one-way street.

The U.S. Government, in its patent policies, even under the license procedure, takes a license which is available not only to the U.S.

Recognizing that a large number of new developments will not merit substantial attention and support, the conditions necessary for success would be rather difficult for a Government exploiting agency to apply. In general, to carry a development from invention to commercialization, as was said by Dr. Hornig, requires very substantial additional investment. I will deal later on with the kind of examples which Senator Long cites. The added costs after invention frequently amount to between 10 and 100 times as much expense for debugging and commercializing inventions as is the cost of the initial invention itself. This, in itself, is an argument against any "windfall theory," that any developer who retains inventions made in the course of work for the Government receives a largely unearned bonanza because to make any such inventions useful, will generally require substantial additional expenditures. It is not proposed that the Government should undertake these further speculative investments.

It likewise ordinarily requires that the individual or organization who is going to make the substantial additional investments have reasonable assurance that he will have a period of time in which to recoup his costs. It is very important to understand how this works. If from the outset individual or organization A undertakes to develop something by plowing additional costs into it, and organization B can sit by doing nothing, but knowing that it can copy the nonexclusive development as soon as organization A has shown how to do it, this is no inducement to A to make the further investment necessary to commercialization. The reason is that B, the copier, will have the advantage of reproducing the item without the added costs and will, therefore, have an actual advantage over A. This is why, in general, nonexclusive licenses do not lead to further capital investment or further development costs. It is the reason why almost all further exploitation is based on exclusive licenses at least for a period.

Now to deal with the kind of examples which Senator Long has cited. It is a fact that some new developments can be put to use with no further investment. If, for example, a fertilizer has been developed which is simply a different mixture of chemicals than those used

work and bring it to a status where it can be of service, can be of general use in the field that it is intended to serve?

You say it sometimes takes a great deal to further process it, further develop it, get the bugs out of it, to get it where it will operate effectively and efficiently. Where the Government takes these patents, who is going to do that? What will it require to get that further development?

If the Government takes title, to inventions as they are developed under its contracts, it gets the discovery; it gets the initial patent we will say or the initial right: it owns it. But how is it going to get further developed?

Mr. HOLST. Well, to date, two suggestions have been made. One has been practiced. One is to make licenses available, either nonexclusive royalty free licenses or——

Senator MCCLELLAN. If you make nonexclusive licenses, I don't know how there is a great deal of incentive.

Mr. HOLST. Under a nonexclusive license, no one has any incentive to do anything.

Senator MCCLELLAN. Would the Government have the right to grant an exclusive license to someone to further develop it?

Mr. HOLST. It seems to me that they would, and if they are seriously interested——

Senator MCCLELLAN. Is that provided for in either of these bills?

Mr. HOLST. I would think so. It is a natural legal right which follows from ownership.

Senator MCCLELLAN. All right.

Mr. HOLST. The first alternative is for the Government to license it. The second alternative would be for the Government itself to undertake and carry the development forward.

Senator MCCLELLAN. I don't think too much of the Government undertaking to do that. There may be exceptions where the Government could very well do it, but generally I would think that the Government would not be equipped to do it, and would, therefore, have to rely upon some private enterprise for the further development.

inventions and get into the business of trying to make commercial products out of them, general experience would suggest that this is not something for which public funds should be used. This is particularly the case in the event you can so arrange the law to provide incentive to get this kind of risk taken by the private sector. It is desirable that such speculation be made by the private sector so that when they fail it is private rather than public funds which are lost. If they succeed it will be because private individuals are willing to work around the clock to make a success of the projects.

I have been discussing some of the requirements for launching new developments, Mr. Chairman, but I think we have said enough, because I much prefer to answer questions than be making points in the abstract——

Senator McClellan. Well, I don't know whether I am very helpful or not.

Mr. Holst. Yes, you are doing fine.

Senator McClellan. I don't know a great deal about this.

Mr. Holst. I would like to mention some benefits which accrue to the Government through widespread use which are not always recognized. If the private sector undertakes to carry inventions forward to commercial utilization, not only will the public get the goods and services, but the Government itself will benefit.

For example, if a commercial organization carries forward a development, let us say in air conditioning, which is smaller, lighter, and quieter and has been developed for a military application, and makes the further necessary investment to adapt it so that it is foolproof, and can be widely used. You now have a new commercial item which is available to the public, and the public obviously benefits from this.

But the Government itself gets many benefits, which are not always self-evident. They need to be appreciated. If the originator of the equipment will undertake to develop for public use and it becomes a volume item the following benefits will be obtained: (a) Its cost will fall, (b) its reliability will undoubtedly increase, (c) it will continue

This takes time, takes further expenditures, and it takes a way of dealing with ownership which is not that recommended by S. 1899.

In summary, Mr. Chairman, we believe that your bill, S. 1809, with some of the added thoughts which we have suggested, forms a good basis for developing a realistic patent policy. Such policy must recognize not only the contributions but the requirements of both of the parties. At no time have we suggested that the Government should not have the full right to use developments for its own governmental purposes.

We consider it important that Government patent policy will attract the most able organizations, enlist their wholehearted enthusiasm, so that the personnel in such organizations are glad to work on Government assignments, rather than seeking to avoid such assignments. There is data that such avoidance and withholding of support does take place. We also consider it important that Government patent policy is such as is most likely to result in bringing application of new developments to a useful reality.

Senator McCLELLAN. Thank you very much, Mr. Holst.

Mr. BRENNAN. Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association.

Dr. Smith, will you please identify your associates for the record.

## STATEMENT OF DR. AUSTIN SMITH, PRESIDENT OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY THOMAS J. BEDDOW, THOMAS P. CARNEY, AND GEORGE E. FROST

Dr. SMITH. The witnesses who accompany me today are more expert in some areas being explored than I am.

Two of them are prepared to be of assistance as we discuss S. 1809, S. 789, and S. 1899, and the third will assist me in trying to be helpful in relation to S. 1047.

The two witnesses who are with me for the first three bills are identified in the statement which has been placed in the chairman's [illegible]. Very briefly, one is a chemist who has long experience in re-

The Pharmaceutical Manufacturers Association, on whose behalf I am appearing, is a trade association representing 136 manufacturers of prescription drugs and related products. Our members produce more than 90 percent of the Nation's total prescription drug output. We respectfully invite attention to the historical fact that there has been no important development in recent decades in drug therapy in which member firms of Pharmaceutical Manufacturers Association have not played a significant role, either in the discovery of the agent or in defining its utility and making it readily available in useful and dependable form to the medical profession.

Our member firms invent, develop, manufacture, and distribute products which relieve suffering and prolong and save life. During the last 30 years, the U.S. drug industry has become the world leader in developing new medicines. Of 604 major new drugs made available worldwide since 1941, nearly two-thirds originated in this country, with only a relative handful coming from other than private industrial research. New drugs have been a major factor in bringing about an astonishing reduction in death rates.

The results of these advances can be measured in terms of health, lives, and also dollars. More than 4 million Americans living today would be dead if 1935 death rates had continued. These 4.5 million survivors' contribution to gross national product has been estimated to be $10.4 billion in a recent year. The decline in the number of mental hospital patients below the number predicted 9 years ago has saved approximately $4 billion in institutional construction costs alone. Drug treatment for tuberculosis has been so effective that between 1956 and 1964 the number of beds required for tuberculosis patients has been reduced by approximately 50 percent, and many TB hospitals have been closed or converted to other uses.

Although drugs are not solely responsible for this remarkable record of medical progress, they unquestionably deserve a substantial degree of credit. One statistic alone dramatizes what has happened. Of the more than 775 million prescriptions written in 1964, it is estimated that 70 percent could not have been filled in 1950, for the simple reason that the drugs prescribed were not then in existence.

These developments are attributable to many factors. One is the enormous research program of the pharmaceutical industry which, since 1949, has increased eightfold. In 1964 alone, research and development expenditures were almost $300 million—bringing the ethical drug industry total to well over $2 billion since 1950. It is important in this connection to note that every dollar of this $300 million came from the ethical drug manufacturers' own funds. Less than $11 million of additional research money was accepted from the Government for conduct of pharmaceutical research.

Between the time of original discovery in a research laboratory and the final

be maintained and extended. It is now Government policy in Great Britain to patent discoveries made in universities and other similar institutions through the National Research Corporation.[2]

Before discussing the specifics of the bills now under consideration, let me express the basic principles that we believe should be followed.

(1) Provision should be made in substantially every case for the issuance of exclusive rights to an industrial concern to assure that drug inventions resulting from Government-financed research really are developed and marketed.

(2) Where the Government is the sole or prime developer in the field of the invention, it is equitable and rational for the Government to hold the proprietary rights and receive royalties from an exclusive licensee marketing the invention.

(3) Where the Government is not the sole or prime developer in the field of the invention, the contractor should hold proprietary rights.

We believe that by following these general principles, the results of Government-financed research will be made available to the public and that the effect of Government-financed research in depressing industry-financed research will be minimized.

We note that President Kennedy's 1963 memorandum on Government patent policy states similar principles. In his words:

"C. The use and practice of * * * inventions and discoveries (made during the course of Government-financed research) should stimulate inventors, meet the needs of the Government, recognize the equities of the contractor, and serve the public interest.

"D. The public interest in a dynamic and efficient economy requires that efforts be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiatives to this end, and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under Government contracts. Where exclusive rights are acquired by the contractor, he remains subject to the provisions of the antitrust laws."

Unfortunately there has been a departure from these principles in the case of inventions concerned with the public health. Various Government agencies, primarily the Department of Health, Education, and Welfare, have applied the Presidential patent policy statement of October 10, 1963, in such a fashion that a drug company associated in the development of a new drug with a Government grantee can almost never expect a reasonable reward for its contribution. To a Government contractor in the pharmaceutical industry this indicates in advance that no matter how small the financial contribution of the Government to the making of the invention; no matter how great the

has been a coincidence of conception and research on their part and that of the USPHS-supported investigator."

6. "I should like to express my strongly held opinion that the present policy of the Public Health Service regarding patents is an extremely restrictive and stultifying one. It is a fact that certain kinds of screening in medicinal chemistry are done well only in commercial firms and to adopt policies which in effect bar the cooperation of academic chemists and pharmacologists in pharmaceutical firms is to my way of thinking very shortsighted."

In order to supplement the above expressions of opinion the research director of one of our member firms communicated with a number of individual researchers and 76 colleges and universities. I think the views of these individuals will interest the subcommittee, and with your permission I will submit a compilation (exhibit I) for inclusion in the record.

It should be emphasized, Mr. Chairman, that in the vast majority of practical cases, the work under a Government-financed research project does not take a possible pharmaceutical beyond the stage where it may be called interesting. Generally, the investigator—be it a company or an individual contractor—does not carry the compound beyond the stage of displaying some pharmaceutical activity. Whether the compound will solve any medical problem, whether it has side effects that offset whatever useful activity it may have, whether it can be developed to a form suitable for manufacture and sale, whether an effective new drug application can ever be obtained, are purely conjectural. During the wartime emergency program to find an antimalarial drug, for example, some 12,000 drugs were compounded and many tested for a malarial activity, Only a handful of these compounds were ever tested on humans. We have had other instances of a similar sort. It is basic error to assume that whenever a possible drug comes within the broad definition of an invention to which the bills apply, that such possible drug has been pursued to any point beyond indicating that it is of "interest" as a future drug.

I should like to direct the balance of my statement, Mr. Chairman, to the provisions of the three specific bills before your committee; to discuss the effect which certain of these provisions would have, in our opinion, on future medical research; and to submit certain suggested amendments to S. 1809.

The three pending bills, S. 1809 (McClellan), S. 789 (Saltonstall), and S. 1899 (Long) are, as you know, directed to the acquisition by the Government of proprietary rights to inventions made in the performance of Government-financed research. In addition to these bills, the October 10, 1963, memorandum of President Kennedy warrants consideration, as well as the practical administrative experience that has developed under this memorandum.

The intent of S. 1809 and S. 789 is to recognize and follow the principle that many inventions will not reach the public unless exclusive rights in some form

There is an additional problem in connection with the compulsory licensing provisions of all of the bills. In each instance, the inventions to which the bills apply are defined in very broad terms; namely inventions which are conceived or first actually reduced to practice in the course of or under the contract (S. 1809, sec. 2(h)). If a contractor expends a million dollars of his own money on an invention and an additional $10,000 of Government money completes the first actual reduction to practice, the compulsory licensing provisions apply to the invention to exactly the same extent as when the Government expends the million dollars and the contractor expends $10,000.

We think that this is wrong, not because of the broad expression of the inventions to which the bills apply, but, rather, because the compulsory licensing provisions apply in each and every case without exceptions. Should such provisions become law, a prospective contractor with a substantial investment in an invention will have no course but to decline Government-financed research. Yet such contractors can provide the Government with a most important existing base of experience and facilities. In some instances, a contractor with an existing investment in research may enter into a contract but refrain from using existing inventions in the performance of the contract for fear that such performance will complete an actual reduction to practice. Under the bill neither the agency head nor anyone else can relieve the contractor of this inequitable and highly undesirable result.

This problem can be handled by an appropriate addition to section 3(b)(5) of S. 1809. Such addition is incorporated in the specific language suggested in appendix A. It is a narrowly framed provision that would enable the agency head to accommodate this particular situation.

We have one additional suggestion. We believe there is a need for a uniform policy throughout Government on inventions made during the course of Government-financed research. This is one reason this legislation is being considered. We believe that this objective of uniformity will be best achieved by two additional provisions. One would provide for rulings by a single board on all questions requiring hearings, such as declarations of acquiring under section 6(a) of S. 1809. In addition, we suggest that a single organization, perhaps along the lines of the present Patent Advisory Panel to the Federal Council for Science and Technology, should be given the power and responsibility of providing, to the maximum extent possible, common procedures and policies in the field throughout the Government.

Finally, we commend the authors of S. 1809 and S. 789 for what we believe to be well-considered and organized bills. We believe that S. 789, or S. 1809 with the modifications suggested above, would be constructive legislation.

We are appreciative of the opportunity to present our views on the important bills before you. We will be happy to answer any questions you may have concerning our presentation.

cles, and research well and happily carried out will increase the incidence of such miracles.

Let us not begrudge the money used for so good a reason, nor the profit of a commercial industry after a success, because this profit will be the foundation of the successful or unsuccessful research which will follow.

AMALIA FLEMING.

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LETTER FROM DR. H. W. FLOREY (UNDATED)

I have been intimately associated with the work of introducing penicillin to medical practice. It was in my laboratory that a group of workers discovered its systemic chemotherapeutic properties in 1940 and first tried the drug on man.

In 1941, with my associate Heatley, I came to the United States seeking assistance from Government and industry for the large-scale production of penicillin, since at that time it seemed unlikely that the valuable new therapeutic agent would be produced in England in sufficient quantity. Many felt at that time that it was practically impossible to manufacture this substance on a large scale as it was so unstable and was present in such minute quantity in the fermentation broths. However, we received a favorable reception from some companies and from Government agencies.

One of the most important steps taken by those investigating the product in the United States was the utilization of deep-tank fermentation. This was accomplished by the chemical engineering skill of the investigators in the United States. Furthermore, strains of the fungus yielding far more penicillin than the original strain were developed; first by looking for better natural strains and later by inducing artificial mutants by means of X-rays, ultraviolet light, and so forth. The first three industrial companies in the United States to join this work were Pfizer, Squibb, and Merck.

The task of developing a practical fermentation process for producing large quantities of penicillin so vitally important to the war effort of the Allies could not have been accomplished without the major contributions made by the engineers and technologists of the American pharmaceutical manufacturing industry. The problem of producing penicillin in quantity was solved in a relatively short time and the drug became available first to the Armed Forces and later to civilians.

A great deal of effort was also expended in attempting to achieve a practical total synthesis of the antibiotic. Despite years of research by many laboratories the molecule did not yield to a practical total synthesis although its complete structure was elucidated by groups working in Great Britain and the United States who kept in close touch during the war.

The process of extracting penicillin from fermentation broth could have been patented and I now believe that such a patent application should have been

which the institution could if necessary license other industrial firms in keeping with the public welfare. Suitable guarantees of diligent development of the compound by the company could be agreed to. Obviously the licensing would be under the more precise terms of a suitable business arrangement involving royalties to the academic inventor or his institution; such a policy is equitable to all concerned, it would be in keeping with public welfare, and it would restore and promote the academic/industrial collaboration which is so essential to bring much of the present research efforts in the health field to fruition and to stimulate more research in the area.

This matter is of vital importance to the climate of academic research and to the welfare of our country. I am wondering if the American Association of Land-Grant Colleges and State Universities might not be interested in discussing it in some detail. If this should be true and we could be of any assistance in providing information and bringing the matter before the association, we would be glad to do so.

Sincerely yours,

GLENN E. ULLYOT,
*Associate Director of Research and Development.*

EXCERPTS FROM REPLIES TO DR. ULLYOT'S LETTER

I am in complete agreement with your point of view in this patent matter and I hope you are successful in getting a change made in the recent rulings. You cannot afford to test samples from universities which are made by the aid of Federal funds under the present rules.

C. S. MARVEL,
*Professor of Chemistry, the University of Arizona.*

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It has been my opinion that the patent policies of the various Government agencies have been shortsighted and harmful.

It is my opinion that new discoveries usually will not be commercialized and made available to the American public unless (a) the Federal Government wishes to procure the subject matter item for defense or war purposes, or (b) unless some industrial organization is granted an exclusive license so that they can afford the expense of development and promotion with good prospects of getting a return on the investment.

If the right to practice the invention is available to everybody (nonexclusive licensing), it is unlikely that any one organization will gamble the funds necessary for developmental and promotional work when a second or other organization can step in and "reap the harvest" without having had to take much gamble.

While I recognize that the practical results of work which is being supported by grants from the U.S. Public Health Service should in some way be made available to the sponsoring agency, the present patent policy has contributed to a drying up of the fount from which discoveries may flow.

The investigator who has no facilities at his disposal to evaluate the compound he has prepared (and most of my colleagues in chemistry departments fall in this category) finds himself confronted with a dilemma. On the one hand, he is required to show, in order to secure grant support, that the compounds he isolates or encounters will be adequately tested. On the other hand, he cannot find a pharmaceutical company to test his compounds because industry has decided that they cannot afford to do so without sacrificing their legitimate interests. The academic investigators, and eventually the public, are the losers.

WERNER HERZ,
*Professor of Chemistry, The Florida State University.*

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I approve wholeheartedly of your proposal and wish it all success.

LOUIS F. FIESER,
*Professor of Chemisty, Harvard University.*

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The problems that you raise are indeed important and I am happy to have your comment. I think it is very probable that during the fall I will have occasion to take this matter up with our own university administration.

H. E. CARTER,
*Head, Department of Chemistry, University of Illinois.*

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I am active in these matters on a subcommittee of our science advisory committee here at Indiana University, as well as the ACS (American Chemical Society) Committee, and I am happy to receive this opinion.

I am forwarding a copy of your letter to Mr. George Heighway of our alumni foundation office. He is quite active in patents for our university.

E. CAMPAIGNE,
*Professor of Chemistry, Indiana University.*

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meantime, we have many new compounds accumulating which we find it impossible to have adequately tested for biological activity.

NORMAN H. CROMWELL,
*Wilson Professor and Chairman, Department of Chemistry, the University of Nebraska.*

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I trust in the future our own patent committee will make the position clear to the National Institutes of Health that the present patent policy is restrictive and in large measure unworkable. An arrangement as outlined in your letter to Dr. Ellis would protect the interests of all parties and I hope ultimately their position will be altered along these lines.

J. H. FELLMAN, Ph. D.,
*Associate Professor of Biochemistry, University of Oregon Medical School.*

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I agree 100 percent with your reasoning and will discuss your suggestions with our Purdue Research Foundation people to get their reaction.

JOHN E. CHRISTIAN, Ph. D.,
*Head, Bionucleonics Department, Purdue University.*

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Many of us have been concerned about the patent policies of the Public Health Service, and I am enclosing a copy of a letter I recent wrote to Dr. Helen L. Jeffrey in reply to her inquiry as to whether we had been able to make proper arrangements for testing compounds we propose to prepare under an NIH grant.

MARSHALL GATES,
*Professor of Chemistry, the University of Rochester.*

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Dr. HELEN L. JEFFREY,
*Executive Secretary, Medicinal Chemistry, a Study Section, Division of Research Grants, National Institutes of Health, Bethesda, Md.*

In regard to arrangements for testing compounds made under the proposed grant, we have extremely good relations with a number of pharmaceutical houses who have been happy to test our substances in the past, and we should, of course, prefer to continue to collaborate with them. It is our understanding, however, that most such firms will not undertake testing of compounds prepared under programs supported by the NIH because of the patent policy adhered to by the

I feel that the present Government policies regarding patents ensuing from Government-sponsored work in the universities are so restrictive as to completely remove any incentive on the part of the investigator to become involved. This can only be to the detriment of the public, for to bring the invention from the laboratory bench to the bottle on the druggist's side shelf requires a very enterprising middleman, viz American industry. The present policies have effectively cut out that middleman by interfering with the communication between the university laboratories and the pharmaceutical laboratories.

C. DAVID GUTSCHE,
*Professor of Chemistry, Washington University.*

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I have made an honest effort to try to understand the Government position on this patent matter. It may be that this patent policy was designed in order to provide pressure for the Government to be involved in more and more screening programs and to come more and more into direct competition with the pharmaceutical companies at all levels. Although you did not mention the fact, I am sure you are aware that it is a requirement that an investigator indicate that he will have new compounds tested before he is awarded a grant.

Now if the pharmaceutical companies had taken an unreasonable position, then my analysis might be different; however, it is my considered judgment that the pharmaceutical companies are making a reasonable interpretation of paragraph 3 and are completely justified in not placing in jeopardy their proprietary interests.

CALVIN L. STEVENS,
*Chairman, Department of Chemistry, Wayne State University.*

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It is most timely that you are surveying opinion on the problem of patent rights regarding prospective drugs and therapeutic agents.

It would seem that a reasonable formula could be developed which would at the same time provide incentive for pharmaceutical organizations and university investigators and protect the public welfare.

The present policy is an administrative oversimplification, which although supposedly is for the purpose of protecting the public welfare, will in the long run be detrimental to it.

GARDNER W. STACY,
*Professor of Chemistry, Washington State University.*

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To: Dean George P. Hager
From: Mr. G. Willard Fornell
Subject: USPHS patent policies

I appreciate your sending over the tentative draft of the study sections statement regarding USPHS patent policies. There seems to be an attitude among Government policymakers that to make a profit from the development of a discovery arising out of Government-sponsored research is morally wrong. Nothing could be farther from the truth. Since but a small part of USPHS research results in a discovery of commercial value, it is almost always necessary to not only allow some firm who will pioneer it to make a profit, but to protect that firm under patents so that it is willing to proceed and thereby make the discovery available to the public.

It seems that the study section has performed a very worthwhile task in probing the areas of (1) conception of inventions [and] (2) how much or little support (either in dollars or percentage of a project) entitles NIH to claim title to inventions. Institutions such as ours which depend heavily on Federal support should never lose the right or the attitude that it is proper to make constructive criticisms to improve the relationship. Government patent policy is certainly an area in which there is room for improvement.

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It is my opinion that the patent terms of the National Institutes of Health and the Atomic Energy Commission, as these are set forth in grant and contract instruments for research with nonprofit agencies, are somewhat less than fair in that they claim all rights to patents.

At the same time Congress has dictated that allowances for indirect costs (overhead) shall be limited to 20 percent of direct costs, usually exclusive of the direct costs for equipment. This about half pays for the real indirect costs of the university. Accordingly, the university makes a financial contribution to each project it undertakes for the NIH. One might expect this would be recognized and at least rewarded by the opportunity for participation in any benefits to be realized from patents which arise in the course of the work.

CARL J. CHRISTENSEN,
*Coordinator, Cooperative Research,*
*University of Utah.*

Senator MCCLELLAN. You may summarize it, Dr. Smith.

Dr. SMITH. Following this summary, Mr. Chairman, each of us will try to develop the facts in greater detail. We would like to give a few specific suggestions and avoid as much as possible theoreti-

I am very interested in the approach that you are taking, and any success that you have in relaxing the rigid restrictions of the National Institutes of Health will be greatly appreciated. I am referring the information which you sent to our Patent and Copyrights Committee with a request that they consider the suggested lines of attack which you made.

ROBERT E. LYLE,
*Professor of Chemistry, University of New Hampshire.*

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I agree that the Public Health Service patent policy makes it difficult for candidate drugs made in universities to receive adequate attention. Without help from industry we cannot realize fully the value of our synthetic work.

R. C. FUSON,
*Department of Chemistry, University of Nevada.*

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This is something that my colleagues and I have been concerned about. Actually, we have a further problem at Northwestern in that the university's patent policy is much like that of the Government. We think that both ought to be changed and are working to change the university's policy.

F. G. BORDWELL,
*Professor of Chemistry,*
*Northwestern University.*

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I am in agreement with your ideas, and have sent copies of your letter to our vice president in charge of research.

ARNE N. WICK.
*Chairman, Department of Chemistry, San Diego State College.*

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I think your suggestions appear to be eminently satisfactory for this ticklish problem.

V. GEORGIAN,
*Department of Chemistry, Tufts University.*

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I agree with you 100 percent. Many of the compounds which I produce are potential pharmaceutical agents. Yet, they cannot or will not be tested simply because the Government has first claims and a pharmaceutical company will not

As I understand it, PHS patent policy exists primarily for the protection of the public interest. Possibly this purpose can be fulfilled in a manner that would allow the inventor as well as the university to profit from an invention, and would permit private organizations to exploit the invention under contractual agreements with the inventor and his institution. The possibility seems well worth exploring.

WALTER J. GENSLER,
*Professor of Chemistry, Boston University.*

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I was rather ignorant about this problem until quite recently when I was approached by the Shell Laboratories to provide some samples for them, and was somewhat shocked to discover the rigidity of the patent clause for grants sponsored by the Public Health Service.

I do not wish to imply that I feel the Government should give away all of its patent rights in these cases, but I agree with you that the policy is much too stringent and hampers cooperation between university workers and pharmaceutical companies.

C. G. OVERBERGER,
*Dean of Science, Polytechnic Institute of Brooklyn.*

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I know very well that unless one can get the cooperation of a well organized and flexible testing laboratory, proper pharmacological testing, including the all-important general screening for unpredictable activities, is nearly impossible. Perhaps the commercial testing facilities that exist can do part of the job, and academic investigators can do another part, but a good deal might be missed by testing under such conditions.

The large pharmaceutical firms, on the other hand, are uniquely capable of providing the kind of testing which, combining imagination with serendipity, can discover the unexpected and open up a new field of investigation. Somehow a way should be found to make it possible again for such organizations to participate in academic research in medicinal chemistry in a way that will protect the legitimate interests of the public, the investigator, and the industrial company.

T. A. GEISSMAN,
*Professor, Chemistry, University of California, Los Angeles.*

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The NIH patent agreement, as it now stands, is quite unsatisfactory and I think should be amended as early as possible. Unfortunately, too many people

the discovery and may contribute much to its development must give up any rights to the drug.

Many university scientists have objected to this policy. It puts a barrier between science and industry that has already slowed down the process of discovery and development.

A research director at Smith Kline & French Laboratories wrote to the president of the American Association of Land-Grant Colleges and State Universities suggesting that the association consider this problem. The letter is reprinted on the next two pages. He also showed a copy to several academic scientists. They requested copies to present to their university administrations. He then sent copies to chemists in 76 colleges and universities.

In their replies the academic scientists almost all agreed that something should be done to restore the collaboration between the industry and the universities. Excerpts from the scientists' letters are given here. They strongly defend the university-industry partnership that has contributed so greatly to the discovery of new medicines.

RESEARCH AND DEVELOPMENT DIVISION,
SMITH KLINE & FRENCH LABORATORIES,
*Philadelphia, Pa., August 20, 1964.*

DR. ELMER ELLIS,
*President, University of Missouri,*
*Columbia, Mo.*

DEAR DR. ELLIS: I have become aware of your role as head of the American Association of Land-Grant Colleges and State Universities. Therefore, it occurred to me to inquire if you may possibly be interested in the question of Government patent policy in the health field and its impact on university/industrial relations.

As you undoubtedly know, the Government claims patent rights to all inventions developed under Public Health Service grant sponsorship. Further, it is not presently general PHS policy to grant an exclusive license for a reasonable period to an industrial firm which might wish to develop and bring to practical application the invention of an academic investigator. This, of course, is a serious matter to a firm and frequently is a deterrent to proceeding with costly development work. In addition, an academic investigator in the health field who chooses to collaborate with industrial colleagues must under certain circumstances secure the signature of his industrial colleagues indicating acceptance of a PHS patent agreement. I enclose a copy of this agreement in case you have not seen it. This agreement, particularly paragraph (3), might be construed in such a way as to jeopardize the ownership of inventions exclusively developed within the industrial organization; for example, if an industrial firm were to evaluate for the therapeutic properties compounds prepared by an aca-

"~~(3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, or where the Government has been the sole, principal, or prime developer of the field, and the acquisition of exclusive rights at the time of contracting might confer on the contractor a preferred or dominant position; or~~

"~~(4) the services of the contractor are for the operation of a Government-owned research or production facility, or for coordinating and directing the work of others.~~

"*(1) is in a field in which the Government has been, at the time of contracting, the sole or prime developer and in which the national security, public health or safety requires close control of further development of such invention and its use; or*

"*(2) is in a field in which the Government had been, at the time the contract was entered into, the sole or prime developer of the field of science or technology involved, and had provided all or substantially all of the funds required for research, development, or exploration activities; or*

"*(3) requires development of a field of technology which is entirely new without significant commercial or private history and would not be likely to be developed in the foreseeable future without substantial Government financing; or*

"*(4) shows the likelihood that any inventions actually reduced to practice under the contract will have depended to a substantial degree upon the prior or parallel conceptions and work of other parties under Government contracts where Government financial assistance has been utilized; or*

"*(5) is intended to produce one or more end items the use of which is likely to be required by law in furtherance of the national security or the public health and safety.*

"In exceptional circumstances *in cases within this subsection 4(a)* the contractor may acquire at the time of contracting or upon disclosure of the invention, greater rights than the nonexclusive license specified in section 3(b)3 if the agency head certifies that such action will best serve the public interest."

## APPENDIX B

### LETTER FROM MRS. ALEXANDER FLEMING (UNDATED)

My husband, Dr. Alexander Fleming, discovered penicillin and its properties in 1928. Since then he knew and had made sure that penicillin was harmless when injected into the animal's body and harmless to human cells and tissues, and that, therefore, it could be used therapeutically. And he said so. Yet in spite of these repeated efforts some 14 years had to elapse before penicillin could be used for the treatment of human beings, years during which thousands of patients who could have been saved died. Why?

Because of lack of means to employ a first-class chemist and buy adequate equipment to purify the crude stuff so that it could be injected. This was achieved

however, to confine such cases to those where there is a clear exception to the need to encourage contractor perfection and marketing of the invention.

To illustrate the problem, we note that section 4(a)(2) of S. 1809 provides for acquisition of proprietary rights at the time of entering into the contract where "the purpose of the contract is for exploration into fields which directly concern the public health, welfare, or safety." There is a similar provision in section 1(a)(2) of the memorandum of President Kennedy.

This provision, we submit, is unwise. When the purpose of a contract is to explore in the fields of public health, welfare, or safety it is more important—not less important—to encourage the perfection and marketing of inventions. No different economic principle applies because an invention results from such contract than otherwise. The choice faced by a business enterprise is simply one of further investing or not investing in an invention and the decision turns on whether further investment is or is not justified by the prospect of monetary return. The case which has been made for contract ownership of title as to inventions generally is equally applicable whether the purpose of the contract is to explore fields which directly concern public health, welfare, or safety or where the purpose of the contract is otherwise.

As an illustration, consider the case of a business enterprise in the plastics industry. If such a concern had a contract for Government-financed research directed to a new plastics material for use in military aircraft, the contract would normally provide for contractor ownership of inventions under section 4(c) of S. 1809. If such a concern also had a contract for Government-financed research directed to a plastics material for use in a prosthetic device, such a contract would normally provide for Government ownership of inventions under section 4(a) of S. 1809. If an invention in a particular plastics material were made on the aircraft contract, the contractor would have the principal or exclusive rights and an economic incentive to perfect and market the product for civilian use. But if an invention in a particular plastics material were made on the prosthetic device contract, the contractor would not have principal or exclusive rights and would not have that incentive. Yet it might and probably would be far more important in the public interest to have the plastic material invention perfected and marketed in the prosthetic device case than in the case of the aircraft.

We use the above illustration because it is in a field where there is definite experience. The provision of section 4(a)(2) is similar to that of section 1(a)(2) of President Kennedy's memorandum. The Patent Advisory Panel to the Federal Council for Science and Technology has interpreted and applied the provisions of section 1(a)(2) of the Presidential memorandum.

The Panel has stated as an example of a case where the principal or exclusive rights should normally be taken by the Government "* * * where the contracts are for the development of products or processes directly related to the public

The report's appendix 4 deals largely with management of the collaborative Cancer Chemotherapy National Service Center. The reviewers did not judge the CCNSC unsatisfactory, but they blamed its patent policies in part for the lack of followup of possible anticancer drug effects.

"It should be noted that many compounds found to have no carcinotoxic activity but which possess other biological activity have not been studied further because of patent, contract, and other restrictions * * *."

Further, in a March 4, 1965, letter to Senator Lister Hill, chairman of the Committee on Labor and Public Welfare, commenting on an amendment proposed by Senator Russell Long to S. 512, 89th Congress, the President's chief adviser on science and technology, Dr. Donald H. Hornig, noted:

"Industry often needs to be encouraged to make the additional investment and to take the risk involved in development needed to carry the invention which has been patented to the point where the product is ready for public use. The risk and cost can be very substantial in such areas as the long and costly processes of screening and preclinical testing of potential drugs prior to the filing of new drug applications since only very few of those tested are ever successful.

"Where the original research is not aimed at the production of new compounds, there may be little interest either on the part of the research group or industry in pursuing the screening and testing of new compounds without patent incentives. This has been clearly demonstrated to my personal knowledge in the case of a distinguished university scientist and his research group which is engaged in research financed by both private and Federal funds. He cannot get the compounds produced under the federally financed work screened, although as a class they are known to be physiologically active. Prior to the present regulations, they were all screened by industry and a number proved interesting."

Dr. Hornig went on to cite the view of Dr. K. M. Endicott, Director of the National Cancer Institute, that the option to permit limited exclusivity can be critical to realizing the full potential of the cancer program. In a most illuminating letter dated March 2, 1965, Dr. Endicott informed Dr. Hornig's office about the frustrations of applying the Government policy as he calls it, in the "real world of getting the research done and bringing the results to bear on the actual prevention and treatment of cancer."

Dr. Endicott concluded his letter most forcefully by expressing his belief in the need for "a flexible instrument which takes into account the equities of the parties concerned, which provides a better inducement to the inventor himself, and which encourages a greater industrial participation in the solution of health problems."

Finally, the academic community has pointed to the need to revise Government patent policy in this field. Let me cite just a sampling of comment

We emphasize the importance of past, current, and prospective private industry research in the pharmaceutical field because it can be frustrated by an inept policy as to Government-sponsored research. Millions of dollars of Government funds are being expended in research related to drugs. The public will get a poor bargain indeed if the effect of this expenditure is to destroy the incentives in our industry and control the development and marketing of new rugs. This can happen. It surely will happen if patent rights are in effect obliterated whenever any Government funds are involved.

We all agree that regardless of the source of an invention the public should have the benefit of that invention. Let us not delude ourselves, however, that dedication of patents to the public accomplishes this objective. Merely making a drug invention does not cure anyone of any disease. The marketing of an invention does. Before the results of an invention are available, risk investments must be made in clinical tests, obtaining an effective new drug application, and marketing. These investments may run into millions of dollars. It is industry—not Government—that must be relied upon to make this investment. The best assurance that the required investment of talent and money will be made comes from the providing of incentive to the pharmaceutical industry in the form of reasonable ownership rights.

A vivid example of the fallacy of dedication is found in the case of penicillin. In 1929, Sir Alexander Fleming's classic technical paper on penicillin was published.[1] It reported how a bacteriolytic substance was found on a contaminated culture plate, how staphylococcus colonies became transparent and were undergoing lysis, and how additional experiments demonstrated that staphylococci and pneumococci were "very sensitive" to the substance while gonococci and meningocci were found to be "sensitive." The paper even reported that the material had low toxicity as demonstrated by tests on rabbits and man. In short, the basic information as to penicillin were ascertained and reported by Fleming in 1929.

Almost 10 years passed before Chain and Florey undertook the further investigation of penicillin that led to its ultimate availability to the world. In 1941, they had purified a sufficient quantity of the drug to undertake a trial on a human subject. It was at this point that the work was transferred largely to the United States. The development of the drug was then pursued as an urgent wartime project by the Government and the pharmaceutical industry, and the steps leading to large-scale clinical testing and ultimate product use were taken. By 1944 the value of the drug had been fully established, and it was available in quantity for use by the armed services.

Here is a case example of a drug—one of the most important of all time—that for about 15 years existed in test tubes, but was not in practical use. It would have been a bargain at any price to have this drug available 10, or even 5, years

(The statement of Dr. Smith referred to follows:)

STATEMENT OF AUSTIN SMITH, M.D., PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. Chairman and members of the subcommittee, I am privileged to appear before you today to present the views of the Pharmaceutical Manufacturers Association on S. 1809, the chairman's bill on Government patent policy and S. 789 and S. 1899, bills introduced by Senator Saltonstall and Senator Long on the same general subject. With your permission we will present a separate statement on S. 1047, a bill introduced by Senator Harrison Williams that deals with the protection of industrial property from theft.

My name is Austin Smith. I am a physician and president of the Pharmaceutical Manufacturers Association. For some years I was editor and managing publisher of the Journal of the American Medical Association and the other scientific publications sponsored by that association. I am chairman of the board of directors of the U.S. Committee and Council Emissary of the World Medical Association, and have served as executive editor of the World Medical Journal.

I have served in various official capacities for bodies such as the U.S. Pharmacopeia, medical and other organizations, universities, and scientific societies. I also am a member of a number of professional and scientific associations.

I received my degree, M.D., C.M., in 1938 from Queen's University, Ontario, and a master's degree in medical science from the same university in 1940.

I am accompanied by Dr. Thomas P. Carney and Mr. George E. Frost, who with your permission will assist in presenting our position and answering questions.

Dr. Carney received a degree in chemical engineering from the University of Notre Dame in 1937. His master of science and doctor of philosophy degrees in organic chemistry were conferred by Pennsylvania State University in 1939 and 1941. He also attended the University of Wisconsin for postdoctorate studies in organic chemistry.

He is the author of the book, "Laboratory Fractional Distillation," and a contributing author of "Medicinal Chemistry" (two volumes,) "The Alkaloids," and "Organic Techniques." He also holds a number of patents on chemical products and on chemical and distillation processes and has been a frequent contributor to scientific journals with papers on anesthetics, analgesics, and other chemical derivatives.

He is a member of the American Chemical Society and is a member and past chairman of its Indiana section. He is also past national chairman of the American Chemical Society's medicinal division and has served as a member of the executive committee of both the organic and medicinal divisions. He is a noted lecturer and a member of numerous professional and scientific organiza-

motivate the use of this technology by those who originate it, if possible. The reason why I say this is because, based on actual experience in trying to transfer technology from one development to another, we have found that the more intermediaries that intervene and require transfer of know-how and motivation from the point of origin to the point of use, the more steps there are, the more likelihood of failure of communication.

It is a fact that the public is not crying out for innovation. They have to be persuaded, they have to be sold. Why is this? Because they do not now have the product, therefore they don't visualize it. Likewise, between having new techniques available and actually motivating someone to set up a business to use them involves many additional considerations beyond the questions of (a) what was the invention and (b) how did it work? There are many additional important problems including how much capital will be required, how large is the market, what will the competition be? Many, many questions must be answered, which are not easy to answer in most cases, and which become less and less likely of satisfactory answer the further away from the point of origin you are trying to get the development used.

So to the largest extent possible it is logical to try to encourage further development by the one who originates it, particularly if the new development is in that organization's own field of activity. This morning you heard Dr. Hornig say, and the Department of Defense has repeatedly said, that they try to find contractors to work with their agencies in the fields in which the contractor is already well established. These organizations are therefore usually able to understand the new developments, their potential, and their requirements. This is contrary to taking them away and then making them available to anyone else.

Senator McCLELLAN. In other words, it is reasonable to expect that one who has devoted a great deal of effort to a given project in a particular area of research would have some headstart over one who had not, and, based on the experience thus far gained, would be able to

To make a new invention truly useful to the Nation requires far more than the issue of a patent, or the disclosure of an invention on paper. If it is not produced in the form of goods or services, the invention, while "available," may be a scientific miracle, but is on the shelf and not very useful. I mentioned before that it is only in a relatively limited class of cases that the original invention can be used in its original form. In most cases it will require substantial additional investment to carry the development forward to useful application. In many cases this further investment is not made by the inventor. It is made by his employer or by an entirely new group, a group that we may call the entrepreneur. He has to raise money or put added investment into the further development and ultimate development of plant, production processes, and marketing techniques.

It has been the experience of organizations performing the entrepreneurial function and carrying forward developments—and our company is engaged in assisting in doing this, we see this in operation—that you cannot attract bank funds or investment funds unless the ownership of the patent, or an exclusive license, assures the organization making the added and substantial investments that its new product or new service, which it has gone to considerable expense to develop, cannot be copied immediately after it is put on the market.

If it is not given some opportunity, within the restricted limits of patent protection and no wider, to stand a reasonable chance of being first, until some other organization has been put to roughly equivalent cost to develop something else, then the necessary investment cannot be attracted to bring about the further development and ultimate marketing of new concepts. Merely making a license "available" does not cause this sequence of events which is necessary in almost every instance, if new inventions are to be truly useful. Mere availability on paper will not create a great deal of public good.

Senator McClellan. Well, if the Government granted an exclusive license in some instances the contractor would be the one making the further development. Do you feel that if he got an exclusive license for a period of years, that he could afford to make the investment?

Our patent law requires that for a valid patent to be obtained, there must be a description of the invention which (1) first of all is clear enough so that others in the field can practice the invention, and (2) that it clearly defines what is protected by the patent and what is not protected by the patent. Present day U.S. patents are not like the salt monopolies or patents of old England. To be valid a U.S. patent must disclose a novel contribution. They cannot be granted merely to convey a right to market something which already exists. Moreover, to be valid a patent disclosure must be not only novel but also sufficiently clear that others may practice it. If the patent lacks these characteristics, it is not a valid patent. In any case it will expire in 17 years. Thus a U.S. patent creates something new which did not exist before and the inventor's rights to his creation are limited both in scope and time.

But long before it has expired, in fact from the moment it issues, the patent is an open document which teaches all competitiors and all others interested in the subject matter what it is that the patentee has invented, what it is that he is doing; and by the same token, what others must engineer around in order to avoid infringement. The history of patents is that as soon as a patent comes out, this stimulates and promotes competition to get around or improve on the new disclosure. In turn, because others must engineer around the patent's proprietary disclosure, patents promote further developments, usually of a substantial nature, and all to the benefit of the public.

Now, what must be recognized is that there is an alternative to the open disclosure system of patents; namely, nondisclosure or secrecy. No organization is obliged to patent and disclose and tell its inventions. It could, in fact, try to keep these as trade secrets. But the alternative of trade secrets is not a method which is equally good for the public. It does not promptly disclose advances in science or engineering and teach competition what you are doing and thereby educate everyone in the development, its requirements, and its limitations.

There are limitations to the assurance of protection from trade secrets. But the owner can quite legitimately and legally and ex-

By our suggestion for separating foreign from domestic rights we do not propose that any contractor should be able to prevent proper international cooperation, but that this can be handled through licenses, preferably commercial licenses between private owners here and private manufacturers or users there.

Another matter which I know concerns some of my friends in the Government is the matter of enforcing license rights granted by the Government and the possibility that by its licensing the Government is encouraging the infringement of patents owned by others. This is not so much an exception to the taking of title by the Government as a related matter which it seems to me it would be well to consider.

This question arises at present if the Government gets in the position where it owns patents and licenses others. Must it then protect its licenses by bringing suit against infringing parties? This is of particular concern to the U.S. Government agency if the infringer is a foreign government or a private contractor on behalf of the foreign government. Must the U.S. Government protect its licensees by suing infringers, including governmental infringers?

Senator McCLELLAN. Illustrate just what you mean. Give us a theoretical case.

Mr. HOLST. Yes. I will make it a dramatic case if you will. I have just suggested that the domestic rights and foreign rights should be separated, and indicated that at the moment this is not done.

Let us say that the U.S. Government has taken title to a contractor-made invention and has the right to manufacture an antiaircraft gun. A foreign company begins to manufacture this same item, either for export to the United States or for use abroad. Here we have a situation where the U.S. Government has complete control through ownership or license to use this equipment for itself, and also to employ second sources to procure it. Under the existing policy the U.S. Government owns or controls foreign rights and it must take any action which is to be taken.

But now the foreign government directly, or by asking some foreign manufacturer, has arranged for the manufacture of these guns for

it is practical or feasible or economical as the case may be, but yet there is that potential that it can be done, and will be done in the course of time, but the Government needs it, and needs it now, the question is, What, then, is the equity as between those who have developed it to the point where it is the base for further experimentation and perfection and so forth? What is the equity?

Does the contractor have equity if he contracts to perfect it, to go on with it with Government money? Does he have any equity, or must he lose and surrender that equity and value which he has acquired up to that point, in order to accommodate the Government?

Mr. HOLST. Yes, Mr. Chairman; this is the relevant consideration, and the question is not solely, What are the equities between the contractor and the Government? It is also a question of public interest—which policy will serve the Government's interests best and which will serve the public interest best?

Senator MCCLELLAN. Isn't there the question of equity as to property rights?

Mr. HOLST. Yes; that is correct; there is.

Senator MCCLELLAN. We have a situation here where there are those who believe that all property rights should be taken.

Mr. HOLST. That is right.

Senator MCCLELLAN. Now, on the basis of property rights there does seem to me to be some question of equity. On the basis of what will serve the Government best, if the Government needs it, by helping finance and expedite the research and development, then that serves the Government interest best. How much the Government should pay for acquiring that interest and expediting its work or making available to it that which it needs much earlier is another question. But the first thing, and this ought to be settled, is property rights.

Mr. HOLST. I don't think it is the first question, Mr. Chairman. I think the first consideration is: How do you best serve the Government's primary needs and then the public's secondary needs?

Senator MCCLELLAN. Then there are two questions that are involved.

ment, but some portion of its later cost will be borne by the Government.

In this way years of work culminating in these suggestions which have not yet been fully perfected, but which it appears can be helpfully applied to defense, can be jeopardized by their being offered for the Nation's use. This does not recognize the contractors equity and it does not stimulate competent contractor cooperation.

Senator McCLELLAN. All right, proceed.

Mr. HOLST. So what I have said to you today is that we think that your bill, S. 1809, comes closer than any of the other bills to dealing with the realities of the situation. Nevertheless we want to suggest a few amendments. They are not major, but we believe they will improve the bill.

During the morning you have asked for suggestions. We would like to propose a few. The reason we do this—and some of this discussion is perhaps sufficient if it becomes a part of the committee's report, and need not be in the legislation—is because one of the defects in the President's patent policy memorandum, is that a number of agencies have felt that they could interpret it and apply it in keeping with their own past practice, the policy statement therefore has not brought about the degree of uniformity which was intended. So we believe that some examples can be given of ways in which the provision for waiver of title by the Government under exceptional circumstances would operate and permit inventions to remain the property of the contractor, the Committee can then consider whether to include amendments in the bill or only to describe the examples in your reports.

The first exception I would like to mention is where an invention has been previously made by the contractor but not reduced to practice. It seems to me that if you are to encourage unsolicited proposals which contain original thinking—which all I understand to be very valuable to the Government and in the experience of my own company proves to be very valuable, then in these cases the contractor should receive favorable consideration for retaining ownership of such in-