licenses suffice and incentive to develop civilian uses is needed to inspire creativity for economic growth.

More liberal ways of dealing with inventors and creative scientists will be forthcoming by Government and industry through realistic code of creativity for R. & D. staffs of the Government. This will gradually cause industry to revise their thoughtless ways of treating inventors and bring better awards and royalty without so much legal delays and costs. Creativity will do more than any factor in raising the percentage of economic growth and is the best counter force to Parkinson's laws.

AMERICAN SOCIETY FOR PHARMACOLOGY
AND EXPERIMENTAL THERAPEUTICS, INC.,
Philadelphia, Pa., August 20, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The American Society for Pharmacology and Experimental Therapeutics is gravely concerned over the effects which pending legislation, in particular S. 1809, may have on research programs of university and other laboratories which are supported jointly by both governmental and nongovernmental funds. It is feared that unless the equities of all parties are properly recognized, the traditional collaboration of governmental, academic, and industrial organizations in research and development may be jeopardized, and progress for the benefit of the public thereby stifled. Accordingly, at the business meeting of our membership which was held at the University of Pennsylvania in Philadelphia on August 19, 1965, as a part of our fall meeting, the following resolution was passed which I was instructed to transmit to you:

"The free enterprise system, the source of many benefits to the public health, is based in part on the concepts of patent rights and of the exclusive control of an invention for a limited period. Legislation defining the assignment of inventions made in laboratories and by scientists enjoying support from public funds should preserve wisely the principle of patent protection. The rights of the public to benefit fully from the fruits of public research must be maintained without destroying the basis of collaboration between governmental, industrial, academic, foundation, and other laboratories on which scientific developments depend."

We should like to submit this resolution for the official record.

Thank you.

Respectfully,

GEORGE B. KOELLE, Ph. D., M.D.,
President.

AUTOMOBILE MANUFACTURERS ASSOCIATION, INC.,
Detroit, Mich., June 14, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The Patent Committee of the Automobile Manufacturers Association, Inc. appreciates this opportunity to express its views with regard to the Saltonstall bill S. 789, the McClellan bill, S. 1809, and the Long bill, S. 1899, all of which relate to Government patent policy.

After careful study of each of these legislative proposals, the members of the committee voted to endorse your bill S. 1809, in preference to S. 789, as representing the most reasonable approach to a solution to the problem of determining property rights as between the Government and its contractors in inventions made through the expenditure of public funds. The committee strongly opposed S. 1899.

In endorsing S. 1809, the committee requested that serious consideration be given to the following suggestions for amendment of the bill which they believe will benefit both Government and industry.

In section 3(a), to be consistent with the aforementioned definitions, it appears that the word "person" in line 16 should read "contractor". The latter

term as it is defined in section 2(d) includes the former and makes the language consistent with the newly added provision of section 3(b)(3) which assures a license to the contractor in any event and represents an important consideration.

As you are aware, American industry as a whole has not looked with favor on compulsory licensing such as is contemplated under section 3(b)(5). This provision could be rendered somewhat more palatable by the insertion in item (a) thereof of a minimum time interval, following the issuance of the patent such as 5 years, during which the patent owner could develop the invention to the point of practical application. This follows the existing philosophy of the NASA patent waiver regulations (title 14, pt. 1245, subpt. 1, Code of Federal Regulations).

The provisions of section 3(b)(8) for forfeiture of any rights where the contractor was found to have knowingly withheld a prompt and full disclosure are indefinite and susceptible of misconstruction. The terms "prompt and full" are subjective in the context used since ideas and innovations are intangible and not readily identified as to time of conception. Such time varies depending upon whether the bare idea or the practical embodiment of the idea is referred to for determination. Similarly, the requirement for a full description makes such requirement dependent on how far the idea has been carried to practical embodiment. It should be noted in this regard that the term "disclosure" has been defined in section 2 to cover a complete description, it being understood that this means such description to the extent available so that the contractor does not have to go out on his own to complete the description. Accordingly, it is urged that the reference to "prompt and full" be deleted from line 4 and from lines 12 and 13.

As regards the term "knowingly," this should be clarified to cover intent to avoid compliance with contract requirements. In the performance of any R. & D. contract, the contractor must always make a judgment as to whether an invention is reportable under the contract and when he does so in good faith on an informed basis, he is doing so knowingly. Accordingly, it is urged that line 12 be amended to insert" and in bad faith" after "knowingly".

Section 3(b)(9) would be more properly rewritten as a separate section in the bill since it would be unusual to require contract language interpreting the language of the act. It is also urged that the language be clarified to assert a positive prohibition against depriving the owner of background patent rights without compensation. The taking of such rights without compensation is considered to be inequitable and contrary to basic legal principles.

In section 4(a)(2), we again direct your attention to the practical impossibility to define or limit the application of the provision especially as it concerns the term "public welfare." It would be preferable to substitute for "welfare or safety" the phrase "safety or security and the inventions likely to result would be useful directly in such fields."

Since the final paragraph of section 4(a) in lines 18 to 22 inclusive on page 7 of the bill paraphrases section 1(a)(4)(ii) of the Presidential memorandum and statement of policy issued October 10, 1963, there appears to be no reason for omitting the additional provision of that policy. This can readily be achieved by the insertion of the following in line 22 of the bill:

"Greater rights may also be acquired by the contractor after the invention has been identified, where the invention when made in the course of or under the contract is not a primary object of the contract, provided the acquisition of such greater rights is consistent with the intent of this section 4(a) and is a necessary incenive to call forth private risk capital and expense to bring the invention to the point of practical application."

In section 4(b), lines 7 through 11 on page 8 of the bill, the head of the executive agency involved is given the right to take title to any invention made even though the invention does not come within the scope of whatever standards for taking title have been set up in section 4(a) upon a finding that "the public interest would suffer" if the contractor got title. Such a proviso is totally without reason and is considered to be entirely improper and unfair. Under such conditions, a potential contractor would have absolutely no basis for believing that he would under any circumstances be entitled to ownership of an invention made under a contract. Personalities and politics would have full reign under such a legislative device.

The committee recommends that lines 7 through 11 on page 8 in section 4(b) be deleted without substitution. This revision would also require that the

reference to section 4(b) in line 14 on page 9 under section 5(a)(1) should likewise be stricken.

To insure that any patent application filed by an agency head may be properly identified, it should be filed in the name of the inventor or inventors. This necessitates the insertion of the phrase "in the name of the inventor or inventors" in section 7 at line 21, page 13, after "invention" and in section 8(a) at line 18, page 14, after "application."

It is further recommended that the last two sentences in section 8(a), beginning in line 23 on page 14 and all of section 8(b) be deleted in their entirety. It has ever been the philosophy of Government since the report and recommendations of the Attorney General to the President by Attorney General Tom C. Clark in 1947 that the public interest would best be served by opening Government-owned inventions to the general public and that licensing of such inventions for a royalty is not only difficult and likely to be inequitable but would necessitate detecting and prosecuting infringers.

To the end that this bill would comply with the foregoing recommendations of the Attorney General, section 8(b) should be changed by the entire deletion of its present text in lines 3 to 11 on page 15 and substituting "Every citizen of the United States shall have a free right to practice the invention covered by any patent to which the U.S. Government acquires title."

The members of the AMA Patent Committee desire to commend your efforts in presenting the bill, S. 1809, and specifically oppose the Long bill, S. 1899.

Respectfully submitted.

WILLIAM L. SCHERER,
Secretary, Patent Committee.

STATEMENT BY ANDREW J. BIEMILLER, DIRECTOR, DEPARTMENT OF LEGISLATION, AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

Mr. Chairman, my name is Andrew J. Biemiller. I am director of the Department of Legislation of the American Federation of Labor and Congress of Industrial Organizations. I appreciate this opportunity to set forth our position on legislation to clarify the patent policies of the U.S. Government.

The basic principle which is the foundation of the AFL–CIO concern with the patent policies of the Federal Government is that all patents developed with public funds should be in the public domain.

At present, this general principle is followed by most Federal agencies. With the major exceptions of Department of Defense contracts and National Aeronautics and Space Agency contracts, any patent issued on inventions made by a contractor with a Federal agency is issued to the U.S. Government. The contractor receives a nonexclusive, royalty-free license, and the patent is available for use by other firms through cross-licensing procedures.

Federal Government expenditures in research and development have risen over the past 10 years from about $3 billion to $15 billion. This outlay is not likely to get any smaller in the foreseeable future and, indeed, is likely to rise still further. The Department of Defense is now spending R. & D. money at the rate of about $7½ billion a year, and NASA alone hands out some $4 billion to $5 billion a year in R. & D. funds.

The Federal Government spends at least two-thirds of the Nation's R. & D. money, and about 60 percent of these public funds go to 10 giant private corporations. The U.S. Government has made an enormous investment in research and development in defense and nondefense activities.

Invention has become big business. The lonely inventor in his own private workshop is the exception today. Seventy percent of all patents are issued to corporations.

Clearly there is a big public interest in the spending of public funds which bring profits and progress to private business. Furthermore, there is a serious danger that public funds will subsidize private monopoly. This will occur if the giant corporations hold exclusive patents on federally subsidized inventions. We oppose the use of public money to strengthen private monopoly.

In 1947, Supreme Court Justice Tom Clark, then Attorney General of the United States, issued a report containing this statement on the issue before this committee:

"When patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest re-

quires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform the research work; will avoid undue concentration of economic power in the hands of a few large corporations, will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free, competitive enterprise."

We agree with this view, and we urge this subcommittee and this Congress to take the same enlightened view of the public interest in patent policy.

We see a basic inconsistency in efforts of giant corporations in support of Federal patent legislation that would make it difficult, if not impossible, for a Federal agency to establish Federal ownership of federally subsidized inventions. These corporations are asking for a privilege which most do not grant to their own employees. Individual inventors employed by such corporations do not acquire patent rights to their inventions. The patent rights pass to the employing corporation.

We do not bring to this subcommittee detailed expertise in the complex field of patent law and regulation. But we are convinced that any fair and reasonable view of the public interest will suggest that all patents developed by private business with Federal funds should be turned over into the public domain.

With this general principle in mind, we endorse S. 1899, sponsored by Senator Long of Louisiana. Senator Long's bill would accomplish the objective we seek in Federal patent policy, and we urge this subcommittee to approve S. 1899.

Mr. Chairman, I appreciate this opportunity to present the views of the AFL-CIO.

Thank you.

U.S. SENATE,
June 7, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR JOHN: I understand that at your recent hearings on patent practices a statement was introduced into the record of the subcommittee which dealt with the pricing practices of the Ames Co., a subsidiary of Miles Laboratories, Inc., of Elkhart, Ind. In this statement the Ames Co. had been criticized for the price charged for a test kit developed to test for phenylketonuria.

I found that there were several errors contained in that statement when it was originally made on the floor on June 3, 1965, and I made a statement on the floor of the Senate which attempted to set the record straight as far as Ames' pricing was concerned.

I ask that my statement, a copy of which is attached, be included in the record of your subcommittee at an appropriate place.

With best regards.

Sincerely,

BIRCH BAYH.

[From the Congressional Record, June 3, 1965]

BLOOD TEST KIT FOR PHENYLKETONURIA (PKU)

Mr. BAYH. Mr. President, recently, on the floor of the Senate, reference was made to the development of a blood test kit for phenylketonuria—known by some of us who are less articulate and knowledgeable in the field of medical science as PKU—which has been marketed by Ames Co., a subsidiary of Miles Laboratories, Inc., a well-known 80-year-old Elkhart, Ind., pharmaceutical manufacturer. This blood test promises to save thousands of infants from mental retardation and, when broadly accepted, will be a remarkable advance in medicine.

I should have prefaced my remarks, when I referred to those of us who are less knowledgeable in the field of medical science, by excluding the present Presiding Officer, the Senator from New York (Mr. Kennedy) because I know of his long interest in the field of mental retardation and mental health.

This test method was conceived by Dr. Robert Guthrie, of Buffalo, N.Y. In performing the test a drop of the infant's blood is used to determine if the child is afflicted with PKU. If undetected and untreated, brain damage occurs with

subsequent mental retardation; however, early detection and medically supervised dietary treatment prevent severe mental retardation in most phenylketonuric infants. Such test procedures hold forth a promise of normal, happy lives.

The Ames Co. undertook the development of the Guthrie test method and has marketed a technically refined product.

The discussion on the Senate floor was based on certain data supplied by the Public Health Service and the Children's Bureau of the Department of Health, Education, and Welfare. There were certain inaccuracies in this data which should be corrected for the record.

To set forth the general position of Ames, I would like at this point to quote from a letter to the shareholders signed by Walter A. Compton, M.D., president of Miles Laboratories, Inc.:

"Our Ames Co. has been involved in PKU research for nearly 10 years. In 1958 it pioneered in developing and bringing to market a urine test to detect this condition, and has in intervening years very materially increased knowledge and attention to this preventable mental disease throughout the world. While not an important product in terms of sales volume, this test has performed a significant role in medicine since, if used routinely, it could lead to the substantial improvement, perhaps even virtual elimination, of PKU as one of the causes of mental retardation.

"It was because of Ames' reputation in this field that a Dr. Robert Guthrie brought his test concept to us. This test is done on blood and, although much more difficult and expensive to perform, it may have the advantage of detecting PKU a few days earlier than can a urine test. Ames agreed to manufacture and market a test based on the Guthrie concept and began to do so in the fall of 1963. This proved to be quite an undertaking because a great deal of research time was spent in refining the test to meet essential standards of quality and uniformity. Ten substantial technical alterations and improvements were required before in our judgment the test could be said to be sufficiently reliable for general use. Moreover, a new production facility has been built and equipped to manufacture the test properly because of special requirements inherent in the product. After this, an intensive educational campaign was necessary to get the new product brought to the attention of health authorities and into clinical use; this was a costly undertaking.

"Ames has never had any monopoly position in the market; there are several competing products that we know of. Nor has Ames even approached recovery of its investment in making this product available. The new product was originally scaled from our estimates to be sold at a price resulting in 42 cents per test. After some 5 months of manufacturing and marketing experience, this was reduced to the present level of approximately 21 cents. At this price, if it were possible for every child born in the United States each year to be tested, this would amount to about $850,000. Yet it has been estimated that early detection and the avoidance of institutional care would save the taxpayers $20 million when spread over the lifetime of the PKU victims born each year. This is quite apart from the human misery which would be prevented.

"In summary we believe that your company has acted in the public interest by developing, manufacturing, and bringing into use reliable tests produced under the high standards of quality required for such products. Actually, this test based on the Guthrie concept was made available largely as a public service, without expectation of significant profit, as part of our responsibility as a leader in this field of medicine. We believe it has made a worthwhile contribution. Much more could be said about the inaccurate inferences which have been drawn in the press in this matter but we believe the above represent the responsible and significant facts."

Now let me set forth for the record the points in conflict and in more detail explain the position of Ames.

It has been implied that, by reason of the fact that Dr. Guthrie filed a patent application covering this test method and thereafter entered into a license agreement with Ames, this action resulted in delaying disclosure of the Guthrie test method. This is clearly erroneous. Dr. Guthrie had discussed his test method in public as early as July 1960 at a scientific meeting in London and further publication in U.S. medical journals followed in 1961. Thus Dr. Guthrie's invention was not concealed and was public knowledge almost 2 years prior to the April 1962 filing of a patent application by Dr. Guthrie, and long prior to the

June 1962 agreement with Ames Co. for the development and marketing of the blood test.

It has been implied that the Ames Co. or Dr. Guthrie sought to establish rights in the Guthrie test method contrary to the Government's rights.

If this were the case, I would be highly alarmed. However, the facts are to the contrary. At all times Ames Co. and Dr. Guthrie and his private sponsors recognized that any agreement was subject to the assertion of controlling Government rights. The June 1962 agreement between Ames Co. and Dr. Guthrie was expressly subject to the prior rights of the Government.

I have had an opportunity to read verbatim the contractual agreements. One clause specifically requires that Government laws are controlling and recognized.

Moreover, the suggestion that Ames and Dr. Guthrie were acting independently of the Government's interest ignores the plain fact that—as recognized in the provision that the agreement was subject to the assertion of Government rights—the Surgeon General had the power to review and approve any license agreement and to impose such additional conditions as he believed necessary for the public interest.

(At this point Mr. Young of Ohio took the chair as Presiding Officer.)

Mr. BAYH. Mr. President, yesterday, we had a rather lengthy and, I felt, enlightening debate on the various aspects of our patent law, especially in the field of medicine and health. The Surgeon General has the power of review and approval and has used it extensively. He used it to deny the application in this particular case.

Although the terms or conditions for a license were never resolved, since no license was granted, advisers to the Surgeon General had indicated that if any license agreement were approved, it would be limited to a maximum duration of 2 years and would embody other specific limitations or conditions.

As matters developed, in May of 1964 the Surgeon General—again within his authority—disallowed the granting of any form of exclusive license. In short, Ames has never had an exclusive license, and Dr. Guthrie has assigned his patent application to the Government.

Even though Ames received no exclusive rights for even a limited period, it has continued to serve the public interest by making available a fully developed blood test kit and has by extensive informational efforts directed to the professions emphasized the value of PKU testing.

In this connection, it has also been suggested that the blood test kit originally made by Dr. Guthrie had already been developed and tried, and that further development was unnecessary. This is not true. That product was at best an experimental product for field trial use only.

The product marketed by Ames Co. is not the same product as produced for the field trial. Ames Co. has spent $93,000 in research and development on the product, and a number of significant changes were required to be made in order to produce a marketable product.

While certainly a contribution, it must be recognized that the test product that was being produced by Dr. Guthrie for field trial was being made under relatively rudimentary conditions in a rented house and with only limited facilities available to him. Dr. Guthrie contacted the Ames Co. because he recognized that the product had to be developed and brought out under the direction of a modern pharmaceutical company that had experience and broad skills and facilities available to it, since he knew that Ames Co. had experience in just that kind of testing. Also, it was demonstrated at the time that there were defects in the test, and that further development and refinement of the product was essential before use by the public in general.

Products to aid in the diagnosis of disease require as high an order of assurance as possible that the test results will be accurate. The danger lies, study shows, between false positives on the one hand and false negatives on the other hand. A false positive would cause undue apprehension, although the baby would always be rechecked and the fact that it was a false positive would be confirmed with no harm done. But a false negative—indicating that the disease was not present—could be tragic. This is particularly true in the case of tests for PKU since, if undetected and untreated, the result may and probably will be irremediable brain damage. This is so since corrective clinical treatment must be taken as soon after birth as possible, if the desired results are to be obtained.

A private company cannot distribute a diagnostic test product for public use until all known defects are removed and there is an assurance of reproductibility

of results and accuracy of performance. This care must be exercised not only for reasons of integrity, but also to fulfill adherence to Government regulations and to minimize exposure to civil liabilities. Ames Co. devoted considerable resources and scientific technology in order to develop a marketable product.

Let me specify the additional steps taken by Ames to improve the product to make it marketable, to make it a product of integrity and reliability, and to show that a great deal of effort was required from the time of final testing to the time of selling it over the counter to the public in general.

First. The micro-organism *B. subtilis* ATCC 6051 was changed to *B. subtilis* ATCC 6633 for better standardization. This was necessary because ATCC 6633 was readily available from reputable commercial sources while ATCC 6051 was not. There were available exacting control standards for ATCC 6633 which were not defined for the ATCC 6051 strain of the *B. subtilis* used in the original kit.

Second. The heat dried spore suspension in the original kit was changed to a liquid suspension in a sealed ampule. It was necessary to make this change to secure standardization and to have a reliable means of securing an exact range of viable spores. This could not be accomplished by the original method of heat drying.

The possibility of contamination strongly existed in the original method as spore vials were open to the atmosphere during the required drying procedure. The sealed ampule provided maximum accuracy as to spore addition to the test medium.

Third. Since heat drying was eliminated, the total spore count per ampule was decreased. This refinement was based upon considerable Ames research effort to arrive at a definite spore count per ampule which would result in optimum readability of the test.

Fourth. The glucose content was decreased from 1 to 0.5 percent. The reason for this change—although it appears to be relatively insignificant—nevertheless was to improve the stability of the end product in terms of assuring maximum lifespan from date of manufacture to date of use.

Fifth. Ferric chloride was eliminated to prevent turbidity in the final dissolved medium. This improvement again resulted in increased readability of the test medium, an important attribute of such test.

Sixth. Sodium sulfite as used in the original kit was changed to sodium sulfate in the refinement process to be in keeping with the growth medium described in the Demain study "Minimal Media for Quantitative Studies with *Bacillus Subtilis*," an established reference on the subject to make it uniform to other tests which are conducted throughout the country on other products.

Seventh. The dehydrated medium produced at Ames' direction by an independent source was a definite improvement over the original process. The original method utilized a dry blend of ingredients which was found unsatisfactory in that total drying was difficult to obtain and the method called for numerous stages of mixing and dispensing. This, in turn, required a constant checking of each mixture as it was completed. In changing to the dehydrated medium, Ames was able to achieve definite uniformity of component ingredients, minimize contamination exposure, increase stability, and meet commercial production requirements. This refinement also made the test easier to perform and lessened the possibility of error by the user.

Eighth. Ames' refinement process eliminated the separate vial of dried b-2-thienylalanin used in the original kit. Ames incorporated the b-2-thienylalanin directly into the dehydrated medium. A decrease in concentration of B-2-thianaylalanin was found to be necessary to secure an optimum medium. These changes were pointed toward the good manufacturing objective of securing maximum uniformity of essential ingredients by combining three of the original components into one dehydrated powder and thereafter into one container as opposed to three separate containers originally utilized in the kit. It makes the kit easier to use and more reliable.

Ninth. An additional improvement was the utilization of five plastic trays and covers in each of the Ames kits as opposed to but one plastic tray and cover in every fifth original kit. Ames found it necessary to provide a one-time use tray. The single tray and cover per every fifth kit as originally devised required using the single tray for repeated testing, thus increasing contamination exposure. Evidence of such contamination had been observed in the single tray method.

Tenth. In addition to the refinements set forth above, considerable time and effort were expended in developing quality control procedures and specifications to insure that the product as manufactured in individual batches and from batch to batch would be accurate and effective in testing babies. A few of such specifications and procedures are—raw material testing, moisture control of test medium, identity control procedures, microbiological assay on *B. subtilis* spores, procedures for stability testing of batch file samples at 6-, 12-, 24-, and 36-month intervals ,and finished product testing procedure.

Mr. President, the development and marketing of a product of the nature of Guthrie product is an intricate process. We are dealing with the lives of young babies, just born, and it is important that we go to the *n*th degree to protect their health and safety.

All of this work on the inhibition assay involved substantial use of research personnel and considerable product development, including experimental manufacturing. The Ames quality control methods development group worked out assay procedures for phenylalanin, B–2 thienylalanin, and medium components; this has been expressly commented upon in item 10 above. The microbiology section and the biostatistical section of Ames quality control developed an evaluation method for kit performance which resulted in a consistent procedure for determination of acceptability of the finished kit. This technological accomplishment was once again in addition to the other quality control procedures set forth in item 10 above.

The above summary refutes a charge that no further development was necessary to market the product commercially. This development effort required additional effort, investment, and expense.

Mr. President, there has been a considerable amount of discussion in committee and on the floor of the Senate during the past several months about some unfortunate practices indulged in by certain drug companies. I do not condone them. I do not condone the charging of exorbitant prices. Ames Co. has been accused of charging an exorbitant price for the product that it developed from the Guthrie test method and it has been stated that such product could be produced for $6, including all costs, for a kit containing 500 tests. At the $6 figure, the cost per test would be 1.2 cents per test. Dr. Guthrie had been working under Federal grants for several years during the development of his blood test method. He had received Public Health Service support of more than $250,000 and had received additional outside private support of about $100,000.

In 1962 the Children's Bureau made a grant for Dr. Guthrie to carry out a broad-scale program of field trial of this blood test method. During this project $570,207 was spent by the Children's Bureau to test 404,568 babies across the country. A breakdown of the budget for this project shows the following:

Expenditures of Children's Bureau grants-in-aid funds (title V, pt. 1, Social Security Act) for Guthrie PKU project, fiscal years 1962–64

Special project grant to University of Buffalo (Dr. Guthrie):	
Staff	$120,132
Supporting services (travel, laboratory supplies, epidemiologic surveillance, postage, etc.)	109,864
Test kit materials	61,467
Scientific equipment	3,444
Total	294,907
Cost of PKU field testing by 30 States (formula grant funds under title V, pt. 1, Social Security Act)	275,300
Total	570,207

This table shows the errors in the statistics of the Children's Bureau as to what the product cost to make. I call particular attention to the cost of the test kit materials of $61,467.

Although in several instances the Federal agencies suggest that the cost per test of the Guthrie kit was 1.2 cents per test, this is clearly erroneous. The budget supplied by the Children's Bureau indicates that the actual cost of the test kit materials alone was 9.2 cents per test based on the number of

blood and urine tests—665,902—actually performed during the program. It should be noted that this is for materials cost only and does not include other costs attributable to manufacturing and distribution since it ascribes no labor or overhead. These costs are not defined in the Children's Bureau budget.

Only the cost of the test material is included, and even so the cost was several times the amount of the reliable cost.

It is impossible to determine what the actual cost per test was during the Children's Bureau program. However, it can be conclusively proven that the per test cost was more than 9.2 cents and not the 1.2 cents per test as indicated in the agency statements.

But regardless of what the costs may or may not be for a governmental agency engaged in manufacturing diagnostic products, the pertinent question is what are the costs—and resulting price—of a reputable, experienced private company that must assume all legal responsibility for and stand behind its products. Further, it is impractical to compare the cost or price of the original field trial test unit with that of the Ames product. It would be similar to comparing a model T Ford to a 1965 Lincoln. Although both are for the same function, the model T is obviously a rudimentary form of transportation and the Lincoln is a very sophisticated, highly refined product.

It is important that misconceptions concerning the price of the Ames product be corrected. It is suggested in certain memorandums by the Children's Bureau that the marketed price of the Ames Co. for the Guthrie test kit was $262.50 for 500 tests or more than 52 cents per test. This is inaccurate. The test kit produced by Ames has never been priced at $262.50, nor has it ever been produced in units of 500.

I do not know where this information was obtained. It is wrong. It is erroneous. It is false. In fact, the test kit has been produced only in units of 325 since the inception of its marketing by the Ames Co. The price per test of the Ames kit was 42 cents per test from November 1963 until April 1964. At that time the price was cut to 21 cents per test.

The misconceptions concerning Ames selling price imply an unconscionable profit. This also is wrong.

In this connection I ask unanimous consent to have printed in the Record at this point a memorandum from the vice president of finance for Miles Laboratories, Inc., to the president of Ames Co., Mr. George Orr, concerning a cost analysis made of the Ames Co. PKU blood test kits. I also ask unanimous consent to have printed in the Record at this point—and this is of equal importance—a copy of the examination made by the public accounting firm of Price Waterhouse & Co.

There being no objection, the material was ordered to be printed in the Record, as follows:

"MILES LABORATORIES, INC., INTEROFFICE COMMUNICATION,
"*May 25, 1965.*
"To: George W. Orr.
"From: Joseph H. Hoyt.
"Subject: Ames PKU blood test kits.

"In accordance with your request I have received our sales and cost records in regard to subject product.

"In my opinion, the accompanying statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits presents fairly the data shown therein.

"The unrecovered cost to date of $131,823 does not include the cost of $50,000 for the film, 'PKU Mental Deficiency Can Be Prevented,' nor does it include an allocation for corporate overhead expense, such as executive, legal, financial, or administrative. These items have been excluded because it is felt they may be controversial.

"The records show that our current selling price for the Ames PKU blood test kit is 20.8 cents per test and that our direct production and distribution costs are 6.6 cents per test. However, after making allowance for continuing marketing, research, and divisional administrative expenses, I estimate our total operating cost at 17.4 cents per test. This leaves an operating margin of approximately 3.4 cents per test.

"If Ames is able to sell tests for 20 percent of the total U.S. potential market of 4 million babies, this would produce annual operating margin of some $27,000.

At this rate, assuming no further reduction in prices, it will take about 5 years to recover those costs yet unrecovered at April 30, 1965.

"Prior to April 1964 our selling price was 41.7 cents per test. However, at that time our production and distribution costs alone were 15.1 cents per test. This higher cost was due to heavy quality control charges and other increased expenses attributable to the learning period.

"JOSEPH H. HOYT.

"*Miles Laboratories, Inc.—Statement of unrecovered costs at Apr. 30, 1965, on Ames PKU blood test kits*

"Net sales of test kits from Nov. 1, 1963 to Apr. 30, 1965	$72,243
Costs and expenses applicable to these sales:	
Production	24,380
Distribution [1]	4,141
Advertising	29,025
Selling [1]	22,215
Division Administration [1]	3,589
Total	83,350
Excess of costs and expenses	11,107
Add:	
Cost of research and development commencing in 1962	93,753
Cost of special equipment and facilities	26,963
Total unrecovered costs at Apr. 30, 1965	131,823

[1] Represents division expenses basically allocated as a percentage to net sales. No amounts are included for corporate administrative overhead expenses of Miles Laboratories, Inc.

"CHICAGO, ILL., *May 26, 1965.*

"The BOARD OF DIRECTORS,
"*Miles Laboratories, Inc.*,
"*Elkhart, Ind.*

"DEAR SIRS: We have examined the consolidated financial statements of Miles Laboratories, Inc., and its subsidiaries for the years ended December 31, 1962, 1963, and 1964, and have previously expressed our opinion thereon under dates of February 11, 1963, February 17, 1964, and February 19, 1965. Our examinations were made in accordance wtih generally accepted auditing standards and accordingly included such tests of the accounting records and such other auditing procedures as we considered necessary in the circumstances.

"As a supplement to the foregoing examinations, we have examined the statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits and made such additional tests of the pertinent accounting records and performed such other auditing procedures as we considered necessary in the circumstances. In our opinion, the accompanying statement of unrecovered costs at April 30, 1965, on Ames PKU blood test kits presents fairly the data shown therein.

"Yours very truly,

"PRICE WATERHOUSE CO."

Mr. BAYH. It will be seen that the public accounting firm report supports the analysis.

This memorandum indicates that the total operating costs are 17.4 cents per test leaving a margin of approximately 3.4 cents per test. Against this the Ames Co. is trying to recover costs which to April 30, 1965, were yet unrecovered in the amount of $131,823. The unrecovered costs were largely involved in the research and the development of the product and acquiring special equipment and facilities required for the manufacture of these test kits.

There is a very small potential market for the product, one in which there is little volume and very little hope of profitability. Further, in the highly scientifically oriented pharmaceutical industry there is also the problem of product obsolescence because of new research and technical achievement. Research is now being conducted by other companies in this very area of medicine.

One product is being tested now, which, if it proves to be successful, could make obsolete the Ames product and the product of its competitors.

Therefore it is impossible to project the length of time that the Ames test will be used. It is difficult, then, to insure recovery of the unrecovered costs to date. I do not believe that the present cost is providing an unconscionable profit.

In keeping with its responsibility, Ames Co., has undertaken an extensive program of education concerning this form of mental retardation, and the use of its product for the detection of this condition. Such costs are a part of business operations and must be assigned to the products involved. These costs include such items as medical literature, informative mailings, and scientific exhibits. In this particular case Ames Co., is not assigning to this product certain other educational costs which could be attributed to it.

An example of the latter is the sound motion picture entitled "PKU—Mental Deficiency Can Be Prevented." Ames underwrote the production of this film, which was produced under the direction of and narrated by Harry A. Waisman, Ph. D., M.D., professor of pediatrics, University of Wisconsin Medical School. Fifty prints of this film have been made for Ames' film library. There are an average of 65 to 70 showings per month, and it is estimated that the film has been viewed by well over 100,000 persons. The film is shown to medical, nursing, and medical technician students; hospital medical and nursing staffs; medical, nursing, and medical technician society meetings; and even to college and high school science students. Several State public health agencies have purchased prints of the film—at cost of the print—for their film libraries.

I had the good fortune to see the film. I believe that most Senators would recognize the importance of striking out as forcefully as we can in every way possible to prevent mental illness and mental retardation. If it were possible, we should offer to Ames a type of "Emmy" award for the fine production and the public service that is being rendered by the film.

In summary, an analysis of the expenses for the Ames blood test kit will show that the price is in keeping with good business practices and well within reason. The product is being marketed by Ames Co., at a reasonable price.

Our Nation is becoming increasingly aware of the serious effects of mental illness. Millions of dollars are spent annually in an effort to cure those who are afflicted. In fact, this Congress has recently embarked upon a program which will result in investing significantly higher proportions of our national resources into curing and caring for those who are mentally ill.

Fortunately for our country, men and women of science and medicine in both industry and academic life have recognized the need to do battle against mental illness long before the majority of us in the Halls of Government. Because of their leadership, significant technological accomplishments have been made not only to treat mental illness after it has been diagnosed but to prevent the very occurrence of the disease.

Dr. Robert Guthrie has been one of the academic contributors. He has conceived a test which will help make it possible to save several hundred American babies, boys and girls, and eventually men and women, from being afflicted with mental retardation each year. How much wiser it is to devote resources to try to prevent an illness from occurring than to be faced with the alternative of spending many times this amount of funds and effort for treatment.

Ames Co. industrial scientists had developed a urine test to detect PKU before the development of the Guthrie blood test. Ames urine test, although it may have the disadvantage of detecting PKU a few days later than the Guthrie blood test, continues to be used and has made a continuing significant contribution to medical science. Because of the effort devoted to the cause of mental retardation prevention by Ames Co., many young Americans are whole and happy instead of facing a life-long tragedy of retardation. I, for one, think that Dr. Guthrie and Ames Co. should be complimented for the effort they have made for the development of effective blood tests against PKU and for the effort Ames Co. has made to make this product readily available to members of the medical profession.

We in the Congress and in the State legislatures recognize our responsibility to enact programs which devote more of our resources to an attack against the dreaded mental diseases which are rampant throughout the country. But I believe that we must also recognize that mental illness can be arrested only with the full cooperation of government, industry, scientists, and educational institutions.

I make that statement on the floor of the Senate and take the time of Senators only because I believe it is important that when we make accusations which tend to make such cooperative ventures between medicine, government and educational institutions less than desirable, we are in fact not serving the purpose which we all really wish to serve; namely, rapid elimination of mental illness wherever it may appear and in whatever form it may appear.

BELL TELEPHONE LABORATORIES, INC.,
Murray Hill, N.J., May 24, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights, Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: This is in response to your invitation at the time of introduction of S. 1809, a bill to establish a uniform national policy concerning property rights and inventions, to communicate comments and any proposed amendments to the bill.

We support the bill as a reasonable and balanced approach to the basic question of "title versus license" which underlies the establishment of any uniform Government patent policy.

The following clarifying amendments are proposed for the reasons noted in the comments appended. These amendments do not affect the design of the bill nor do they result in changes in the underlying policies.

Page 3, section 3(b)(1), line 24, change "the prompt and full disclosure" to "a prompt disclosure".

Comment.—This conforms the use of the term "disclosure" in CONTRACT REQUIREMENTS with its definition in section 2(f).

Page 4, section 3(b)(3), line 13, after "license" insert "shall include the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded and".

Comment.—This will avoid placing the contractor in a position of inconsistent contractual obligations. The inserted language has been adopted from NASA's waiver regulations where it has been employed since 1962.

Section 3(b)(3), line 15, after "part" insert a period, strike "and" and insert "Such license and right".

Comment.—This is an editorial modification necessitated by the next previous amendment.

Page 5, section 3(b)(5), line 7, in subsection (a), after "has not" insert "within three years after a United States patent issues on such invention".

Comment.—It would seem that a contractor should have a reasonable time within which to demonstrate efforts to bring the invention to the point of practical application. The 3-year period is the same as that employed in the Presidential memorandum.

Page 5, section 3(b)(5), line 9, in subsection (a) after "practical application" insert "or has made the invention available for licensing royalty-free or on terms that are reasonable in the circumstances".

Comment.—This suggested amendment has also been adopted from the Presidential memorandum. A compulsory license would appear unnecessary if the invention is already available either royalty-free or on reasonable terms.

Page 5, section 3(b)(6), line 16, after "may" insert "timely."

Comment.—Since time is of the essence in preserving foreign rights, it appears desirable to allude to this factor.

Page 6, section 3(b)(8), line 4, after "prompt" strike "and full."

Comment.—See comment above with respect to amendment to section 3(b)(1).

Page 15, section 8(b), line 6, after "granted" (second sentence), cancel "under" and insert "subject to the license reserved to the contractor by section 3(b)(3) and," after "such" insert "other."

Comment.—This insures that the license reserved to the contractor is retained despite the designation of the license in the preceding sentence as "exclusive."

We appreciate the opportunity to comment on your bill and we favor its adoption over the other patent policy bills pending before your subcommittee.

Very truly yours,

E. W. ADAMS, JR., *Patent Attorney.*

NEW HAVEN, CONN., *May 26, 1965.*

Hon. JOHN L. MCCLELLAN,
Senate Office Building,
Washington, D.C.

DEAR SIR: Pursuant to your letter of April 30, 1965, I, as a member of the patent bar, have taken some interest in the current situation which has developed in connection with the Government patent policy. In particular, I refer to S. 1809, S. 1899, and S. 789.

Upon careful review of these bills, I would say that the S. 1899 approach of Senator Long is neither practicable nor acceptable. It misinterprets the purpose of the President's statement on patent policy and creates a situation which is not in the best interests of the public or the contractors. In contrast to Senator Long's bill, Senator Saltonstall's bill includes various and sundry matters, i.e., inventive contributions and awards therefor, amendment to 28 U.S.C., section 1498, etc. In these respects it requires some reflection and perhaps some investigation by the Presidential Commission in order to develop sufficient information as to the necessity for making such changes.

This leaves, for the most part, your own bill, sir, S. 1809, as the bill which should be given careful and most serious consideration by the Congress at this time. However, this bill does require at least some minor changes, primarily centering about the implementation of the Government patent policy, so as to fully develop the benefits to the public as a result of the vesting of the title in the Government. Accordingly, after careful consideration, I should like to suggest the following amendments to your particular bill. I believe these amendments would strengthen the bill.

Page 5, section 3(b)(6), amend to read as follows:

"(6) provide in the event the principal or exclusive rights in any invention are acquired by the head of the agency, on behalf of the United States, and such agency head does not actually file a patent application in order to secure a patent in the United States or in any foreign country before a predetermined time, said predetermined time not being greater than nine months from the date of disclosure of the invention to the agency and in any event not less than three months before the statutory bar date, appropriate means whereby the principal rights in the invention will automatically revest in the contractor if either (a) notice is not given by the agency head to the contractor that a patent application has actually been filed within the above-mentioned predetermined time, or (b) the agency head notifies the contractor that he does not elect to file a patent application in the United States or in any foreign countries before the predetermined time mentioned above, subject to the rights reserved to the United States in subsection (b) (2) of this section;"

Page 8, section 4(b), line 7, after "he determines" add "not later than six months".

Page 8, section 4(b), line 11, add the following sentence: "The agency shall reimburse the contractor for the reasonable expenses encountered in filing a patent application or in prosecution of a patent application in any case where the agency decides to take greater than a nonexclusive license."

Page 15, section 8(a), line 10, after "may be granted" add "only"; after "with" delete "or without."

Page 15, section 8(a), line 11, after "the United States" add: "each agency is required to institute appropriate judicial proceedings to enforce the principal ownership rights of the United States in order to prevent others from using its patents without the payment of appropriate royalties."

In particular, I propose that section 3(b)(6) be amended to provide that if the Government takes title to an invention and does not actually file a patent application within a predetermined time limit, the contractor then be granted the right to regain the title and be permitted to file a patent application, subject, naturally, to the rights reserved to the United States in section (b)(2) of section 3, so that protection will not be lost to both the contractor and the U.S. Government. As section 3(b)(6) is currently written, there are no provisions which make it necessary for the Government to actually file a patent application (assuming the invention is patentable) unless it so desires. If the Government does not file a patent application, then the contractor is not getting what he is supposed to get under section (b)(3) (that is, an irrevocable

nonexclusive royalty-free license for the practice of the invention throughout the world).

If the Government does not file and the contractor cannot file because he does not have title, it is conceivable that someone, at a later time, could file an application covering the same invention and thereby prevent either the Government or the contractor from using the invention. Additionally, there is no justification for allowing the Government to permit inventions to be kept secret or become abandoned or disregarded due to (1) a statutory bar because they have not filed in time, (2) the administration feeling that they have not sufficient funds to file patent applications, or (3) the administration not desiring to file patent applications on selected inventions, unless the contractor is given an opportunity to at least attempt to protect the invention. In substance, in the present clause (6) of section 3(b), you have attempted to accomplish this purpose with regard to foreign rights. It is believed it should be extended to the rights in the United States so that protection will not be lost to the public in general.

With further regard to the present bill, section (6), if the United States did not file an application and the contractor could not file an application, foreign competition could enter into the U.S. market even though the U.S. Government was the first to own the subject invention and could have filed a patent application. This is an additional basis for my belief that the contractor should be given the chance to file in the event the Government does not file a patent application in the United States. Accordingly, amendment of section 3(b)(6) as suggested, should be considered in order to fully protect the Government, the contractor, and the public of the United States.

Additionally, I propose that section 4(b) be amended to place a time limit on the retaking of greater rights than a nonexclusive license where the administrator or agency head believes that public interests would suffer as a result of the contractor retaining the principal exclusive rights in the invention. It is unjust to retake title from the contractor after he has filed a patent application and invested capital for a period of years to exploit the invention. Further, if this occurs, contractors will be deterred from making capital investments until the rights are firmly established. By placing a limitation, such as 6 months, definiteness would prevail and the contractor could then make his plans for exploitation of any and all inventions on which he has, initially, more than a nonexclusive license.

With further regard to section 4(b), I propose that, in all fairness, if the contractor initially files a patent application, he should be reimbursed for the costs of filing and prosecuting it in the Patent Office, if the agency head determines that the U.S. Government shall take greater than a nonexclusive license. Inasmuch as the contractors are not paid for filing patent applications, it would seem fair that if they expend their own funds they should be reasonably compensated in the event that such patent rights are then retaken by the Government after the Government has, initially, permitted the contractor to take the principal rights. This would be in line with the constitutional requirement that property should not be taken without due compensation.

Also, I believe that section 8(b) should be amended so that the agency head cannot grant any license without the payment of royalties. The major contention of the individuals supporting the Government's taking title of inventions is that the contractors have been given title to property belonging to the public, in other words, it is a giveaway program. It seems to me that if we permit a license to be granted on a royalty-free basis that this, again, is just another type of giveaway program. If the Government is going to become the owner of a patent, it should act as an owner. Patent owners do not give royalty-free licenses unless they are given something in return.

As an adjunct to this, I propose that section 8.(a) be amended to require the Government and/or the agency head to institute appropriate judicial proceedings to enforce the principal ownership rights of the United States in order to prevent others from using its patents without payment of appropriate royalties. This

should be made mandatory to prevent a giveaway program from ensuing. Unless this provision is inserted, no one will take a royalty-paying license with respect to Government patent rights. Without a policeman to enforce a patent, there is no justification for one paying the Government for the privilege of using it. It should be the duty of the Government, as the owner, to see that fair and just royalties are paid so that users of the patent are treated on the same basis.

In conclusion, if the U.S. Government desires to become the owner of patent rights, it should be required to function as an owner and, in essence, that requires it to file patent applications and to collect royalties from others using its patent rights. Further, it should actively enforce its patent rights so that no one free-loads on the Government and on other licensees who have risked their capital in exploiting the invention. Without these provisions, the Government system of title will be nothing more than an empty pit into which everything enters and nothing comes out.

It is hoped that you will give these comments consideration during the hearings to be held with regard to Government patent policy.

Thank you for your attention.

Very truly yours,

DONALD BROWN.

THE UNIVERSITY OF MICHIGAN,
COLLEGE OF PHARMACY,
Ann Arbor, August 26, 1965.

Re S. 1809.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
Senate Judiciary Committee, Washington, D.C.

DEAR SENATOR MCCLELLAN: After writing to you the enclosed letter of August 24, I learned of your understanding attitude during hearings last week. Throughout the hearings, I have been particularly impressed with your desire to get the essential facts relating to the development of compounds made under Government sponsorship.

The statements of Dr. James A. Shannon particularly struck at the heart of the problem, and Mr. Walter A. Munns offered a reasonable solution to the problem. However, I wish to add that the principles suggested by Mr. Munn should be worded in such a way that industry will know in advance of testing and development exactly what its rights will be. Otherwise, no agreements will be reached.

Since the spring of 1962, thousands of compounds have remained on the shelves for lack of proper biological testing. Until a law is enacted, the arbitrary restrictions still in effect will continue to serve as a roadblock.

In the spirit of the final hearings, why can not Dr. Shannon's and other health offices of the Government be directed by the White House to disregard present patent restrictions and to use its discretion in the matter of disposition of patentable inventions until legislation has been passed? Otherwise, time, money, scientific advances, new drugs and lives are needlessly being lost because of a fear that the pharmaceutical industry will take advantage of the public.

I am pleased also that the hearing record will remain open until August 31 to permit inclusion of additional statements. I hope the enclosed materials will be included.

Respectfully yours,

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry
(*Past Chairman, Division of Medicinal Chemistry, American Chemical Society*).

Enclosures.

THE UNIVERSITY OF MICHIGAN,
COLLEGE OF PHARMACY,
Ann Arbor, August 24, 1965.

Re S. 1809.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Judiciary Committee, Washington, D.C.

DEAR SENATOR MCCLELLAN: Please let me introduce myself. I am professsor of pharmaceutical chemistry, the University of Michigan, Ann Arbor, Mich. I was born in Columbia, S.C., in 1912, the son of Edward Burckhalter, of Aiken County, S.C., and of Elizabeth Strain, of Fort Smith, Ark. I have spent 5 years in the pharmaceutical industry and 18 years in university teaching. During the past 9 years, I have been a consultant to the National Institutes of Health. Last year I was chairman of the Division of Medicinal Chemistry of the American Chemical Society. In 1962, I became the first recipient of the Research Achievement Award in Medicinal Chemistry, a $1,000 prize sponsored by the American Pharmaceutical Association Foundation. I have directed the research and studies of 28 Ph. D. recipients and 24 post doctoral associates. I am the inventor of drugs for malaria and amebiasis, and important fluorescent antibody labeling agents used for the rapid diagnosis of infectious disease.

Please excuse the rather immodest statement; I wish you to know how deeply I am involved with research in new drugs and, therefore, with Senate bill S. 1809.

Present patent regulations of the Public Health Service have prevented my students and me from having proper biological testing of the products produced under governmental support. It is ironical that the people through its Congress and President specify that research leading to new drugs be carried out, yet regulations instituted over 3 years ago have stymied those efforts and frustrated those of us who are caught in the middle. Thus, the taxpayers' money is being poured down a rathole, in effect. Bright, energetic students especially wonder what is wrong when our Government works at such cross-purposes.

It has been estimated that research representing less than 1 percent of the funds appropriated by Congress for NIH-sponsored research has any chance of leading to new drugs. To realize the great difficulty of finding new drugs, the total research effort of the pharmaceutical industry at a cost of nearly $300 million per year has produced only one or two truly novel drugs each year. Thus, the possibility of finding a new drug is slight under the most favorable circumstances. Present governmental patent regulations and those suggested by Senate bills which would make an exception of health-supported research will greatly reduce, if not prevent entirely, the likelihood of new medicines from Government support.

To go to the other extreme of no control, would it not be better to have the relatively small outlay of money by Government go freely to the universities, if it means assuring development of novel drugs and reestablishing important collaboration between universities and industry?

The Government entrusts universities to choose qualified faculty and research associates to carry out research. It should rely equally upon the universities in regard to the development of patentable inventions. The only controls by Government should be those requiring reports of patent applications and of development of the inventions to make certain that new substances receive proper biological evaluation. In case of improper development, march-in rights could be exerted, which would be in the interest of the researchers, the university, and the public. Also, present or future antitrust laws, rather than legislation restricting instead of encouraging development of new drugs, seem to me to be the proper course for any abuses by industry.

I am deeply disturbed by the inhibitory effect of present patent regulations and by proposed bills which make an exception of health research. I presume to suggest and hope that S. 1809 will make the following provisions relating to Government-supported research.

1. Patent regulations relating to research in the health sciences will follow essentially the same principles as those in other fields.

2. Disposal of patentable inventions should rest primarily with the grantee and his institution, especially when the patent policy of the institution advances public purposes.

3. The Government should retain royalty-free rights to the inventions for its uses in Government hospitals and facilities.

4. The Government should make certain that patentable inventions are being developed by means of progress reports from the grantee and the collaborating company. March-in clauses should be brought into effect in case of improper development.

5. Present and future antitrust laws should protect the public from excessive costs.

6. Industry should be assured of its rights in advance of biological testing.

7. Proposed legislation should make clear in any patent regulations that marketing rights to industry will not be endangered when industry has borne the cost of research. Those rights should not be lost because a piece of equipment or building purchased by Federal funds was used.

I am enclosing herewith my earlier statements concerning the problem. You will favor me greatly by discussing my letter and the statements with members of your committee.

Sincerely yours,

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry, (Past President, Division of Medicinal Chemistry, American Chemical Society).

Enclosures dated June 8, 1962; March 6, 1963; December 23, 1964; and February 22, 1965.

AN OPINION RELATING TO USPHS PATENT POLICY

JUNE 8, 1962.

Now that the patent policy has been spelled out more clearly by the new patent agreement, and blanket patent agreements are apparently not being processed between universities and the office of the Surgeon General, the overall policy is decidedly discouraging to the testing by industry of products made either wholly or in part under NIH auspices. Even before the new regulation was put into effect, industry was wary of testing a professor's compounds. Now there can be no doubt about industry's attitude.

The only reasons why industry would sign the new agreements are—

(1) as a gesture to a professor in order to allow him to receive research funds, but serious testing would probably not be undertaken;

(2) as a means of finding leads which they could independently pursue—in other words, an evasion of the spirit of the unrealistic regulations.

Since serious testing and evaluation of NIH supported products by industry will cease under present policy, the university chemist must look elsewhere for help. There are three alternatives: (1) private laboratories which test for a fee; (2) university laboratories, and (3) Government laboratories. In either case, an expansion of present facilities would be necessary. For the following reasons, I do not believe the expansion of either would be wise:

First, is the fact that industry is already set up to do rapid, efficient screening. Industry's life depends upon this fact. Because of an understandable lack of incentive to produce new drugs, it is unlikely that either of the two alternative laboratories suggested would ever equal industry's potential.

Testing is an extremely expensive operation. The cost of isolation or synthesis of a new substance is often minor when compared to its biological evaluation. The fees of a private laboratory would thus be prohibitive to the NIH grantee.

I have already had experience with testing in several university pharmacology laboratories. In most cases, results simply are not forthcoming—even after several years. The same is true of governmental laboratories with the exception of the crash program of CCNSC. I should be glad to document these cases in confidence.

There remains the broader question of whether or not it is good for our universities and the National Institutes of Health to take on the business of screening. I am opposed to it. Applied, developmental work should not be the province of the National Institutes and the universities. If it were, the next step would be the manufacture of drugs by Government and universities. Do we want to industrialize Government and university laboratories?

The wishes and objectives of Congress who appropriate NIH funds and the people who pay taxes should be considered. First, I believe Congress and the people are primarily concerned with providing effective medication at reasonable cost. Second, I believe that Congress and the people do not want Government or the universities to perform functions which are most efficiently done by industry. Even prior to the new patent agreement form, industry was wary of expending funds for testing potential drugs whose manufacture they could not control. Thus, for years the full mandate of Congress and the people who have

appropriated increasingly large sums for public health research has not been carried out. It is as if a bridge were built except for one section across a wide river. Such a bridge, despite the cost, is worthless. Does Congress want such a bridge? The missing section, in the case at hand, is proper evaluation of compounds made under Government sponsorship. The new patent form makes the problem all the more acute.

Government, as a nonprofit institution, is rightly a paternalistic one. Thus, what does it matter if industry is occasionally subsidized to the limited extent of the cost of initial preparation of a chemical so long as a valuable new medicament is provided? Actually, industry's research costs are increasing, while truly novel drugs are decreasing in number. A small assist to industry in this case is perhaps even more realistic than a subsidy to agriculture.

Actually, the portion of PHS expenditures designed to lead directly to new drugs is relatively small. Thus, dollarwise a cancellation of the patent policy would constitute a relatively minor gift to universities and industry.

There is a moral question concerning the acquisition of patents by the Government when the inventor or coinventor is an employee of a university or institute whose pay comes entirely or largely from the university or institute. In many cases, the research problem was conceived before application for a grant or contract was made, or the inventive idea comes in the case of a university from a professor whose pay comes entirely or largely from his university.

The Government does not purchase an inventor's brains and background when it pays for work done by a student technician or assistant. The great contribution made by Government in medicinal chemistry is in granting money which pays for new basic chemistry and for the education of a student while he makes promising new compounds usually at the suggestion of his professor. Suppose a professor conceives of a superior method for the production of a drug. He happens to assign the problem to a Public Health research assistant (he might just as well have been a Monsanto fellow). Under present and proposed practice, the university could not control the invention. Years of experience, hard work, and study have enabled the professor to plan research. The Government, of course, did not pay for his education and does not pay his salary. I believe, therefore, that the university and the professor should have much voice in the disposal of such inventions.[1]

Here are my opinions regarding proper patent policy involving Government grants and contracts.

I feel a university, industry, or other institution should be allowed to make decisions regarding patentable inventions developed under grants and contracts. Institutions should be encouraged by the Surgeon General's Office to sign letter agreements relating to disposition of patents. The grantee institution should be allowed to offer nonexclusive licenses to industry. In case a particular company developed the invention, it should have a 5-year exclusive marketing of any products.

It is assumed that a grant or contract is let by the Government, because important research or development is not being carried out. The Government cannot allow an area of research important to the safety or health of its people to be neglected. The Government is a nonprofit, paternal organization. Its policies should favor organizations which are astute enough to employ scientists and engineers who can solve important problems. A university or institute should agree to a policy of nonexclusive licensing, except when a particular company did the developmental work. Then, that firm should be granted exclusive marketing of any product developed for at least 5 years.

J. H. BURCKHALTER,
Professor, Pharmaceutical Chemistry, the University of Michigan, Ann Arbor, Mich.

MARCH 6, 1963.

MR. HERSCHEL F. CLESNER,
Inventions Coordinator, U.S. Public Health Service, Washington, D.C.

DEAR MR. CLESNER: First, let me say that your visit to Ann Arbor afforded me much satisfaction. Your receptive and objective attitude toward the problems arising from the present patent agreement form was most encouraging. In accord with your suggestion, I am outlining some of the specific reasons why I hope the provisions can be altered.

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[1] To my knowledge, only Senator Long of Louisiana, Congressman Vivian of Michigan, and Chairman of the Board Boyer of Smith, Kline & French have indicated that the inventor should receive certain rights or rewards. Indeed, creative minds in universities, industry, and Government should receive special reward.

The reasons center around the fact, under present regulations, of industry's unwillingness to engage in the serious testing of compounds developed under PHS auspices, and the NIH grantee's need for pharmacological testing by industry. Based upon my experience and familiarity with industry, testing laboratories, universities, and Government, I believe that the facilities of industry rather than those of the other organizations will bring most rapidly, most efficiently, most economically, and most safely—which is to say to the greatest interest of the public—medicinal agents which are conceived in the universities. Industry's existence depends upon the efficient conduct of screening and it also has the facilities in a single coordinated organization to see that a drug goes over the long series of hurdles. Without patent provisions which will enable industry to participate in the development of a drug, I cannot visualize how an NIH-sponsored drug will reach the people. I shall illustrate the difficulty encountered in our laboratory, under present regulations, of getting over the first hurdle after synthesis—that hurdle being pharmacological testing.

Case 1.—In 1957, we culminated 12 years' effort in the laboratory by the synthesis of a particular compound to be screened in a disease which afflicts about 1 billion persons in the world. Two eminent authorities in the field suggested that only a particular Government laboratory could do the screening, and they expressed great interest in the results. On March 29, 1957, I wrote to the Government laboratory. I have written a total of seven letters and held private conversations with that laboratory in an attempt to obtain the test which is available, but I have failed to secure the evaluation that the two authorities agree should be carried out. The sample is still being held by the Government tester.

Case 2.—On June 26, 1962, we submitted a compound for pharmacological study by a Government facility whose head has expressed in print and orally to me that there is great need for such agents as we have been preparing. Three additional compounds were submitted, the last on November 19, 1962. Acknowledgment of receipt has been made of only the first, and no pharmacological results have been sent to us. I know that screening is currently being carried out, because I visited the laboratory.

Case 3.—A letter and two long distance telephone calls at the expense of my university were made in attempting to reach the head of a Government laboratory which is concerned with a disease that afflicts over 200 million persons in the world. I wished to relay information and to seek to interest that laboratory in the biological evaluation of a nontoxic substance which has shown great promise in animals. No response has yet been received from the director although the initial contact was made on January 11.

Case 4.—Several compounds were submitted about 2 years ago to a professor in a department of pharmacology of a large university. The substances, of potential in cardiovascular disease, were submitted upon the request of the professor. Despite our inquiries concerning results of testing, no response has been received.

Case 5.—Four compounds were recently synthesized in our laboratory under NIH sponsorship; they are identified as GS–82 x 8, GS–82 x 9, GS–82 x 15 and GS–82 x 18. More compounds should follow soon. The substances offer promise in cardiovascular disease. Several of the intermediates are potential anticonvulsants. I do not know where to turn for prompt, reliable testing.

Case 6.—Student ER has recently found how to synthesize types of compounds which offer promise in cardiovascular disease. He, as well as student GS, are concerned about where we can obtain pharmacological testing of their compounds.

Case 7.—Eight compounds, identified as RR–33, 37, 38, 39 and 42; DB–54 x 21 and 24; and IS–71 x 86, are desired by company X as potential drugs. However, their director of research is concerned about their right to market one of them should it show promise. This is a factual situation, even though none of the compounds was synthesized under NIH auspices. The company is concerned lest it might later be shown that some NIH money was expended indirectly during the synthesis. We still hold the compounds, and cannot publish manuscripts until biological data are available.

I realize that in this letter to you it is unnecessary to use arguements growing out of the citing of individual examples of our problems. I am sure from our recent long discussions that we agree on the difficulties. Nevertheless, I shall now take the liberty of generalizing in order to draw a more complete picture in case my letter is examined by a third party who may be less familiar with the implications.

purchased under a Government grant are not used by an industrially sponsored student. (Industry has shown no particular concern over the reversed situation. Ironically, most industrial fellowships in constrast to governmental ones involve no patent agreement; the primary purpose is the support of students in science.) Indeed one of my most time-consuming and harassing duties is keeping separate ideas, students, supplies, and funds based upon sponsorship. The natural demands upon a research professor are so great that he should not be subject to such needless harassment.

Defenders of the present regulations challenge those of us who would change them to offer statistical data in support of our claims. In reply, I use a famous quotation: "There are three kinds of liars: liars, damn liars, and statistics."

How can one obtain statistical facts concerning such a problem as we are facing? Suppose there were a governmental edict requiring that thenceforth all children be taken from their parents at birth and placed in homes for children where they would uniformly receive the best possible education and discipline. After all, it is well known that many children do not receive such advantages at home. How could one provide meaningful statistical evidence against such an edict?

The present patent regulations were made in an arbitrary way. If statistical information was employed in revision of the patent regulations, it pertained to only a portion of the present problem. Present as well as past patent policies of the U.S. Public Health Service failed to consider the necessity for collaboration between scientists in universities and industry. Commonsense tells us that regulations which restrict communication between medical scientists are potentially bad for the progress of science, the economy, and the health of the Nation.

An article in Science (July 24, 1964) describes the importance of collaboration between the two groups of scientists. The fact that foreign nonindustrial researchers outproduced their American counterparts by more than 2 to 1 can be attributed at least partly if not entirely to the fact that the governmental support in America has been very great and, for many years, has been largely self-defeating owing to the requirement of assignment of patents to the Surgeon General. Thus, a large potential of productivity has been ironically dissipated by Government. Scientists from other countries stand in disbelief when they learn of our restrictions.

As a member of an ad hoc committee on patent matters of the Medicinal Chemistry Study Section of NIH, I have suggested that our committee try to obtain certain facts which might be meaningful. But I cannot be too hopeful because the question is one involving principles of economics and philosophy of Government rather than statistics.

Supporters of present patent regulations describe alternate plans as a give-away of public funds to industry. Actually, the regulations are worse than a giveaway to industry.

Commonsense tells us that policy which assigns patent rights to the Federal Government will have the general effect of preventing development of potentially valuable drugs. Industry has made its position statistically clear at least in this regard. Based upon basic principles of economy, their vote has been almost unanimously opposed to testing Government-sponsored products. Under our system of free enterprise, industry cannot afford to pour time and money into developments which it cannot control for at least a reasonable period.

Commonsense tells us that policy which assigns patent rights to the Government will tend to discourage the application for patents. Commonsense also tells us that a policy which either assigns patent rights to the Government or tends to discourage patents is a policy which gives away not only governmental funds but the talents of university scientists to socialistic and communistic countries which own their industries and, therefore, need not obey the rules of private enterprise. Admittedly, these same countries already confiscate industry's patented inventions, but the policy of the Federal Government should not be the ironic one of making further contributions to socialistic countries while simultaneously depriving its industry of the right to develop promising new agents.

In other words, either patent assignment to Government or the failure to patent, can reasonably be said to have the effect of encouraging socialism and communism abroad at the expense of American industry. The policy would also tend to encourage socialism at home, for, if Government continues to expand its support of research under present patent policy, industry will become increasingly a contractor for Government and essentially will be owned by Govern-

holds the fundamental right to decide how his ideas will be developed. The Government violates elemental individual human rights and dignity if it confiscates a professor's knowledge and experience in exchange for financial support for research assistants, supplies and equipment. Such is the case because of the patent regulations. For the sake of freedom of the scientist and the health of the citizen, the regulations should be changed.

JOSEPH H. BURCKHALTER,
Professor Pharmaceutical Chemistry, (Past President, Division of Medicinal Chemistry, American Chemical Society).

FEBRUARY 22, 1965.

THE NEED TO CHANGE PATENT POLICY RELATING TO MEDICAL RESEARCH SPONSORED BY GOVERNMENT

Present patent policy controlling potential new medicines initiated or developed under the auspices of the Federal Government assigns all rights to the Government. Three different bills introduced before Congress a year ago and, presumably, to be reintroduced this year, as presently worded, would enact into law the present practice regarding inventions relating to public health.

The bills are the following: S. 1290 (April 9, 1963), Senator McClellan; S. 1433 (May 1, 1963), Senator Long; and S. 1623 (May 28, 1963), Senator Saltonstall.

Based upon my experience in industry and universities and as a consultant to National Institutes of Health, I contended that the present patent practice and that which is proposed by the three bills, while well meaning, fails to recognize the past fruitful collaboration between industry and universities which has produced approximately half of the drugs being used in the world today. The policies are unsatisfactory to virtually all the pharmaceutical companies and to those scientists in universities whose research is most likely to lead to patentable drugs.

I wish first to suggest amendments to the bills which would promote instead of destroy collaboration between the scientists of industry and universities and, therefore, provide better protection to the health and economy of the Nation. Afterward, arguments will be presented in support of the contention that present regulations and the proposed laws are potentially harmful rather than helpful to the cause of public health and welfare.

SUGGESTED AMENDMENTS

1. The form of the present agreement, which industry will not sign, should be amended so that patent rights to industry's own inventions cannot be jeopardized by testing compounds for university scientists performing Government-sponsored research.

2. The principle that industry has rights as a result of collaboration should be recognized by an agreement in advance of testing and development and not afterward. The collaborating firm should receive a period of marketing exclusivity. Five years is suggested.

3. The Government should allow a university to hold patent and property rights while granting the Government royalty-free rights. The university should have a sound patent policy in keeping with he public welfare, allowing other firms to market a drug at the end of the period of exclusivity.

STATEMENTS IN SUPPORT OF PROPOSED AMENDMENTS

The most immediate difficulty caused by the present Public Health Service patent policy is that grantees cannot obtain adequate biological testing of products of their research. Industry which has superior facilities and personnel for screening cannot afford to expend funds without advance assurance of marketing privileges, at least for a limited period of time.

The logical result of a lack of testing or the inadequate testing of potential drugs is that they will not be made available to the sick.

A second difficulty facing the university grantee is the continued and harrowing experience of keeping records in making certain that equipment and supplies

I feel that the first four cases demonstrate clearly the lack of followthrough which is likely to be evident in institutions where basic research rather than biological screening is the principal goal. Also, I refer back to paragraph 2 of this letter in reference to the efficiency of industry in screening.

The answer to the problem, in my opinion, does not lie in the establishment of screening laboratories in Government and university laboratories. Applied, developmental work should not become a principal objective of the National Institutes of Health and the universities. Nor do I feel that the answer lies in having particular tests carried out under contract with private screening laboratories. In the first place, this plan entails a large expenditure of funds which the grantee or the NIH (i.e., the taxpayer) can ill afford to pay. Secondly, such testing does not provide for prompt, coordinated followthrough at each of the succeeding hurdles which lie ahead in drug development. Only industry has the necessary machinery, but present regulations prohibit serious testing and development by industry which contends that it cannot afford to test compounds they cannot market.

While every investigator would like to see his products in use by the public, actually a more acute problem results directly from the lack of prompt, reliable, and extensive pharmacological screening such as only industry can provide. It concerns prompt publication of results. Manuscripts which describe biologically interesting compounds are considered to be incomplete when at least a summary of pharmacological results is not included in the manuscript. Cases 1, 4, and 7, cited in this letter, describe a situation which has prevented the publication of three or four manuscripts from our laboratory. I shall be glad to furnish confirmation of this fact. (Admittedly, case 1 involves a test which only the Government can at present carry out, but it does illustrate the broad problem of inability to publish because of a lack of biological data.) Case 2 demonstrates the inability of a student to include pharmacological data in his thesis and, later, in a journal manuscript. More important, his training in medicinal chemistry has been greatly curtailed because chemical-biological correlations are impossible. Cases 5 and 6 illustrate the dilemma of my students in regard to current studies. Not only do we need tests for future publication but for guidance in future syntheses. Thus, prompt testing can indicate the direct or future synthesis. We are very reluctant to ask NIH for a supplemental grant in order to obtain contractual testing for reasons already given.

A final consideration is that industry is already equipped to test compounds for the main objective of the grant. Also, industry conducts valuable screening of the same compounds in other biological areas, sometimes as many as 10 to 20 additional tests. A single test has been estimated as costing as much as $1,000, but the costs the grantee and NIH nothing.

Again, let me express the pleasure and satisfaction of spending so much time with you in Ann Arbor in the informal discussion of our problems. Your objective attitude is greatly appreciated.

Best wishes.

Sincerely yours,

J. H. BURCKHALTER,
Professor, Pharmaceutical Chemistry.

DECEMBER 23, 1964.

STATEMENT TO DR. GLENN ULLYOT OF SMITH, KLINE & FRENCH

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of present governmental patent policy defeats the purpose of a grant by preventing the evaluation and development of compounds as new drugs. The obvious, predictable effect of the patent regulations thus constitutes a serious deterrent to essential collaboration between universities, industry, and the Government and, therefore, a blow to the future health of the Nation. Scientists from Britain, France, Germany, Japan, and Egypt have stood in amazement when they learned of our present patent provisions.

Aside from the necessity of such collaboration in public health, the regulations ought to be examined in the light of simple legal and moral codes. A researcher

ment. Such social changes probably were not the intent of Abraham Lincoln when he said that patents add the fuel of interest to the fire of genius.

The question might arise as to why a professor continues to supervise and conduct research under Government auspices when he cannot cooperate with industry in necessary development. An answer is provided in the fact that Government grants support students. Faculty cannot easily refuse such support once it has been established. Professors and students are interested in mechanisms of drug action and in contributing to knowledge in that area. They cannot and do not wish to change these interests, which are directed toward the welfare of mankind. They seek and need the competent assistance of industry for confirmation of their theories and development of their products.

The question arises as to why certain pharmaceutical organizations seek to bring about a change in PHS patent regulations. They are suspected of being motivated by the prospect of profit at Government's expense. This suspicion is indeed well founded. Industry must make a profit to survive. But scientists in industry are also motivated by the wish to resume fruitful collaboration with their academic colleagues and by their desire to help faculty and students test their theories. Nevertheless, virtually all pharmaceutical companies refuse to test PHS-sponsored preparations since they presently have no advance assurance that their investment will be protected and since they cannot risk losing large investments in their own related research. Industry regrets to see the inefficient expenditure of public funds which results from present policy. Herein lies its main concern. Industry does not need the compounds of universities to survive, but we in the universities need the testing facilities of industry in order to train our students and to fulfill our obligations in Government-supported research.

A proper function of Government is to support education and research in neglected areas when needed for the national welfare. Thus, governmental cooperation with industry enables industry to help the economy and to pay taxes so that Government can support education and research in universities. Present patent regulations relating to public health interrupt that cycle, with industry, universities, and the public as losers. The Nation's antitrust laws are designed to protect the public from abuse by industry in all areas. That patent regulations involving drugs should constitute a special case is a mistake created through misunderstanding, emotionalism, and political opportunism. The same basic laws of economics and motivation control the search for new products, whether they be food, armaments, safety devices, or drugs.

JOSEPH H. BURCKHALTER,
Professor, Pharmaceutical Chemistry,
the University of Michigan, Ann Arbor, Mich.

CALIFORNIA RESEARCH CORP.,
San Francisco, Calif., June 16, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Patents, Trademarks, and Copyrights Subcommittee,
Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The following remarks express my views and those of my company on legislation proposed by S. 1809 that would establish a uniform national policy concerning inventions made through research supported by public funds.

California Research Corp., a subsidiary of Standard Oil Co. of California, is an organization engaged primarily in research and development on products or processes related to petroleum. We have in past years undertaken an appreciable amount of Government-sponsored research: but in relation to our total program, this has been a small fraction of our total effort—not exceeding 3 percent in any 1 year. We are glad to undertake such contracts without profit to us where we have a particular background of knowledge or experience that can be of benefit in a Government program.

In my opinion, S. 1809 is a good bill and will provide a reasonable solution to a complex issue. A comprehensive bill of this type establishing basic guidelines of Government patent policy for inventions resulting from Government research is generally consistent with the late President Kennedy's statement of patent policy of October 1963, with which we were also in agreement. We would be opposed to legislation, whether it be a uniform national patent policy or included in

specific research authorization bills, that are contradictory to the guidelines set forth in President Kennedy's statement.

Many private firms such as ours are willing to utilize their background of knowledge and experience on Government-sponsored research projects without profit. The most rapid progress in such projects is usually made when company scientists assigned to it are able to draw freely on the background knowledge the company has accumulated over many years of experience. The Government agency is thus able to obtain the most for their research dollar.

The incentive for a company to undertake Government-sponsored research will be diminished greatly if the price of contributing its special competence is the the requirement that it must give the Government exclusive title to inventions and technical information developed and made possible by millions of dollars of previous company investment in facilities and background research. In our opinion, Government agencies will find it difficult to obtain contracts for research in many cases if this requires the contractor to place in jeopardy his proprietary position.

I do not intend to imply from the foregoing that the contractor should always acquire title to inventions. There are situations where it is reasonable that the Government should acquire title. It is essential that Government administrators be given flexibility to meet these situations without adopting the title policy throughout. S. 1809 recognizes this and we are in agreement with the principles it sets forth.

Certain aspects where S. 1809 could be clarified have been pointed out by witnesses at the recent hearings before the Senate Judiciary Subcommittee, with many of which we concur. For example, the section on compulsory licensing, section 3(b)(4), would be improved, we believe, if the reference to "reasonable terms and conditions" were amended to include "and at a reasonable royalty." However, it is not my purpose at this time to review these suggestions in detail, rather they should be left to the committee to decide on the basis of the various recommendations made by industry representatives.

I believe that S. 1809 provides a proper balancing of private and public interests. It will meet the Government needs while furnishing a reasonable incentive and protection of proprietary rights to companies able to make a real contribution to Government research programs.

Sincerely,

A. H. BATCHELDER, *President.*

DELIO AND MONTGOMERY,
COUNSELORS AT LAW,
New Haven, Conn., June 16, 1965.

Re Government patent policy and hearings with regard to S. 789, S. 1809, and S. 1899.

Senator JOHN L. MCCLELLAN,
Chairman, Senate Judiciary Subcommittee on Patents, Trademarks and Copyrights, U.S. Senate Office Building, Washington, D.C.
(Attention of Mr. Stephen G. Haaser)

SIR: In view of the hearings being conducted by your subcommittee and the importance of such proposed legislation touching on Government patent policy, I should like to submit to the subcommittee for inclusion in the hearing records the views of the writer as chairman of the legislative committees of both the Connecticut Bar Association (Patent, Trademark, and Copyright Section), and the Connecticut Patent Law Association.

If any clarification or discussion is deemed necessary or advisable, kindly let me know.

Thank you.

Respectfully submitted.

ANTHONY P. DELIO.

This is the prepared statement of Anthony P. DeLio, for inclusion in the record in connection with the hearings on S. 789, S. 1809, and S. 1899.

Anthony P. DeLio is the chairman of the Legislative Committee of the Patent, Trademark, and Copyright Section of the Connecticut Bar Association as well as the chairman of the Legislative Committee of the Connecticut Patent Law Association, and submits this statement on behalf of both associations, not to mention various and sundry inventors and corporate patent owners.

Anthony P. DeLio is a former patent adviser of the Office of Naval Research, U.S. Navy Department, and now the senior partner in the firm of DeLio & Montgomery, New Haven, Conn.

The Federal Government's patent policy will have far-reaching effects upon the economy of this country in the years to come and therefore any legislation touching on this area should be carefully construed and considered. Accordingly, the Congress must address itself to the question of the Government's patent policy with well reasoned criticism and understanding.

As one begins an investigation into this area, two policies are evident. One policy is the so-called title policy, wherein the Government takes title to all inventions developed with or as a result of the expenditure of Government funds, while the other policy is the so-called license policy, wherein the Government takes a license under the particular invention, patent, or patent application, leaving title in the contractor.

BACKGROUND

One of the largest Government complexes involved in research and development is the Department of Defense. In the past it followed a license policy with the Government taking title only in those cases where the national security was a factor. Even when the Department of Defense did not take title there was sufficient machinery available to delay the grant of a patent to a contractor so as to ostensibly "kill" the patent or delay its grant to a point where, once granted, it had no useful life.

Perhaps starting with the Atomic Energy Act of 1954, there was a change in thinking in connection with Government-sponsored research and development programs. By certain provisions in this act; viz, sections 151, 152, and 153, the Government would retain title or be vested with title to all inventions useful in the utlization of special nuclear material or atomic energy in an atomic weapon. The Space Act of 1958 contained provisions similar to the Atomic Energy Act; viz, sections 305 and 306, whereby the Government could take title to inventions developed with Government funds. The Space Act did contain some measure of flexibility as to the vesting and taking of title, at least as interpreted and administered by the Space Agency to date.

Due to the legislative programs of the late Senator Kefauver and Senator Long, as regards Government patent policy, the late President Kennedy issued a White House policy statement in 1963 setting forth some guidelines for the Government's policy as to patents. Essentially, the policy statement specifies that the policy is established for all governmental agencies with respect to inventions or discoveries "made in the course of or under any contract of any Government agency, but subject to specific statutes (such as the Atomic Energy Act and the National Aeronautical and Space Administration Act), which specifically provide for the disposition of patent rights."

1. Where the principal purpose of the contract is to create, develop, or improve (*a*) products, (*b*) processes, or (*c*) methods which are intended for commercial use by the general public, at home or abroad, or required for such use by governmental regulations;

2. Where a principal purpose of the contract is for the exploration into fields which directly concern the public health or public welfare;

3. (*a*) Where the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the Government, (*b*) where the Government has been the principal developer of the field;

4. Where the services of the contract are (*a*) for the operation of a Government-owned research or production facility, or (*b*) for coordinating and directing the work of others.

Under such circumstances the Government shall normally acquire the principal or exclusive rights throughout the world in and to any invention made.

In exceptional circumstances the contractor may acquire rights greater than a nonexclusive license if the head of the department or agency (with which the contractor is dealing), certifies that the grant of the principal or exclusive rights to the contractor, will best serve the public interest.

The White House policy statement also specifies that greater rights may be acquired by the contractor (that is, greater rights than a nonexclusive license), if, after the invention has been identified, the invention (1) is not a primary object of the contract and (2) the acquisition of such greater rights is necessary to call forth private risk capital.

In another section of the policy statement it is stated that when two or more potential contractors are judged to have presented proposals of equivalent merit, their willingness to grant the Government the principal or exclusive right in the resulting inventions will be an additional factor in the evaluation of the proposals.

The policy statement specifies that where the purpose of the contract is to build upon existing knowledge or technology for use by the Government and the work is in a field of technology in which the contractor has acquired technical competence (know-how, experience, patent position), the contractor shall normally acquire principal or exclusive rights throughout the world with the Government acquiring at least an irrevocable nonexclusive royalty-free license throughout the world for governmental purposes.

If the principal exclusive rights in an invention are retained by the contractor, (1) the contractor must agree to provide written reports at reasonable intervals upon request by the Government agency on the commercial use that is being made or which is intended to be made of the inventions and (2) the contractor and his licensee or his assignee must take effective steps within 3 years after a patent has issued on the invention, to bring the invention to a point of practical application or in the alternative make the invention available for licensing royalty free to competitors.

Notwithstanding the above, where the principal or exclusive rights are acquired by the contractor, the Government shall have the right to require the contractor to license another on a nonexclusive royalty-free basis.

The Federal Council for Science and Technology, in consultation with the Department of Justice, has been commissioned under this White House policy statement to report annually on the effectiveness of the policy and a Patent Advisory Panel has been established under the Federal Council for Science and Technology to work out the details.

In the 88th and 89th Congresses, Senator Long was successful in attaching riders to several bills; viz., the Appalachia bill and others, which riders set forth a title patent policy for the Government.

In recent months the proponents of the title policy have cited various abuses by those dealing in patents; viz., the PKU situation and others, in an effort to gain support for further title policy riders and/or the adoption of an overall title policy as regards Government financed research and development.

THE DIALOG

Historically, the patent system has proven its worth, especially in those nations where the underlying economy is still basically free. Those who accept this view feel that the adoption of a title policy will weaken the patent system with its attendant ill effects upon the economy and the Nation as a whole. As such, any change in the policy from, say, the flexible Department of Defense (license) policy to a title policy must be carefully weighed and analyzed. In addition, until the proponents of a title policy can guarantee no ill effects upon the economy and, more importantly, upon the investment of risk capital, there should be great reluctance to adopt a so-called title policy.

In view of the foregoing, one basic question that should be considered is whether or not the Government needs title in order to satisfy its needs or requirements. Since the Government is not a manufacturer, since the Government does not make it a policy to license inventions for profit, since the Government has a limited staff of patent specialists and since the Government has little expertise in evaluating inventions from a commercial standpoint, it would seem unnecessary and inadvisable for the Government to take title to inventions developed under Government-financed research and development programs. So long as the Government obtains a license under the invention in question, it and the public interest is adequately protected. The reason is that the contractor cannot sue Government contractors for infringement in view of title 28, section 1498, of the United States Code, which states:

"Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the Court of Claims for the recovery of his reasonable and entire compensation for such use and manufacture. * * *"

Since the Government has a license, the contractor having title to the invention cannot proceed against the Government in connection with the invention in question.

On the other hand, leaving title in the contractor stimulates the investment of risk capital to develop the invention commercially, because the contractor has an exclusive property right in and to the invention. In addition, the contractor is inclined to seek and obtain as much foreign patent protection as is commensurate with the invention's field of use and the contractor's foreign enterprises.

Accordingly, it is appropriate to reflect at this juncture as to whether or not Congress should enact legislation and, more importantly, what type of legislation should be enacted. In addition, might it not be advisable to wait for recommendations from the recently announced Presidential Commission to Study the Patent System, before enacting legislation which will have far-reaching economic effects. It is submitted that the Congress ought to "take a minute" to weigh its responsibility to the Nation in connecton with this matter in order to best serve the public interest.

PROPOSED LEGISLATION

There are several bills pending in the Senate, viz, S. 789, S. 1809 and S. 1899 in connection with Government patent policy, and it is important that these bills be carefully viewed in light of the above.

To begin with, S. 1899 (Senator Long, 89th Cong.) prescribes an inflexible title policy, which takes title where Government funds are expended. Regardless of whether the Government needs title, it must take title under S. 1899. As such, the policy prescribed by this bill is not in keeping with the underlying basis of the Presidential policy statement, nor is it in keeping with the best interests of the public. When title to an invention vests in the Government, when a patent is taken out by the Government, and when the invention and patent become available, royalty free, or otherwise, on a nonexclusive basis to all, little, if any, risk capital will be invested to commercially develop the invention in question. In addition, since the Government is not involved in the business of world trade as an entrepreneur, there is little incentive for it to take out patents in other than this country. As such, there can be a loss of (patent) protection to the United States as an entity, with its attendant loss of licensing revenue, which is a gain for the competition. Accordingly, such a title policy would relegate more and more inventions and patents to the growing graveyard of Government-owned inventions and patents.

As far as S. 789 (Senator Saltonstall, 89th Cong.) and S. 1809 (Senator McClellan, 89th Cong.) are concerned, these bills are ostensibly compromises between the title and license policies, but prescribe in reality no more than a sugar-coated title policy.

Any one familiar with the workings of large corporations or Government agencies is keenly aware that only on rare occasions will the administrator or his aid give up title to an invention, based upon the criteria set forth in these bills. Once the Government has taken title, it will become even more difficult for the contractor to get title back.

In Senator Saltonstall's bill, S. 789, machinery is set up for the contractor to get title back; but in each instance judgments are necessary which would tax the powers of a Solomon. Accordingly, the net result of the Saltonstall bill will be that the Government would invariably take title and in some few instances title might revert to the contractor.

The same applies to Senator McClellan's bill, viz, sections 4 and 5 thereof.

As such, none of the bills currently before the Congress possesses the flexibility of either the Preidential policy statement or the Department of Defense policy.

COMMENTS AND CONCLUSIONS

Under Department of Defense policy, the Government obtains a license under all inventions developed as a result of Government-financed research and development programs. If a policy is adopted which is practically or ostensibly a title policy, it will drive many prospective contractors with the desired and necessary expertise out of the business of Government contracts. In addition, those who continue to seek and obtain Government contracts will be careful to

keep a clear line of demarcation between company-sponsored and Government-sponsored research programs. When research is to be conducted in an area which is sensitive as concerns Government patent policy, the contractor will see to it that no Government funds are used in an effort to avoid any question of the Government's title to an invention or patent. The result is that the Government will not end up with a license—it will end up with nothing. As such, procurement by the Government will be subject to an increasing percentage of propietary rights, which are unencumbered by Government licenses, with the net result that the public interest will not be best served.

In view of the foregoing, it is suggested that a policy must be adopted which is flexible enough to give the Government title in those instances where it is necessary for the Government to have title, but which first resolves the doubt of title in favor of the contractor, reserving to the Government a royalty-free, irrevocable, nonexclusive worldwide license.

In an effort to meet this challenge and to satisfy the requirements for a practical everyday policy concerning Government-sponsored research and development, please find attached hereto a bill which has been approved by the Connecticut Bar Association and the Connecticut Patent Law Association. In many respects the proposed bill is similar in its tone and approach to the bills of Senator Saltonstall and Senator McClellan. It leaves title in the contractor with the Government always obtaining a license and provides machinery and procedures whereby the Government may take title in order to best serve the public interest, viz, the public health, safety, and security.

It is respectfully urged that this subcommittee and the Judiciary Committee of the Senate give careful consideration to the question of Government patent policy and the proposals before them and that each member pause "just a minute" to insure to the public that its interests will be best served by any legislation to be enacted.

Respectfully submitted.

ANTHONY P. DELIO.

S. ____

IN THE SENATE OF THE UNITED STATES

A BILL To prescribe a national policy with respect to the determination and disposition of property rights to inventions made in the course of experimental, developmental, and research work conducted under contracts or arrangements with the United States Government, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Inventions Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) The term "executive department" includes any executive or military department of the United States.

(b) The term "agency" denotes any independent establishment in the executive branch of the Government, the Government Printing Office, the Library of Congress, and any wholly owned Government corporation.

(c) The term "head" used in conjunction with executive department or agency denotes the head of such executive department or agency, except that the Secretary of Defense shall be the head of the Department of Defense and of each military department thereof, and in the case of any authority, commission, or other agency, control over which is exercised by more than one individual, such term means the body exercising such control.

(d) The term "contract" means any contract, agreement, commitment, or understanding entered into between any executive department or agency and any other person for the acquisition of any property or the performance of services by or on behalf of any executive department or agency. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract.

(e) The term "person" includes any individual, corporation, partnership, firm, association, institution, or other legal entity.

(f) The term "invention" means any invention, discovery, or improvement which appears to be reasonably patentable under title 35, United States Code.

SEC. 3. The Congress hereby declares it to be the policy of the United States that—

(a) Each contract entered into by an executive department or agency of the United States and each subcontract at all tiers thereunder, which has as one of its purposes the performance of experimental, developmental, or research work, shall contain provisions prescribed by such executive department or agency governing the disposition of property rights in and to inventions made in the performance of such work thereunder. Said provisions shall state that the contract is subject to the terms and conditions of this Act. Said provisions shall grant to the United States a proprietary interest greater than that set forth in subsection (b) of this section in any invention first conceived or reduced to practice in the performance of such work where a determination by the pertinent executive department or agency that the public interest requires that the Government receive a proprietary interest greater than that set forth in subsection (b) of this section. The determination of whether the public interest will best be served by Government ownership of an invention developed under a contract shall be based upon such factors as whether the contract—

(1) calls for exploration into fields which directly concern the public health, safety or security and the inventions likely to result therefrom would be useful directly in such fields; or

(2) is intended to produce one or more end items the use of which is likely to be required by law in furtherance of the public health, safety or security.

(b) As to those contracts not within the purview of subsection (a), there shall be reserved to the United States in all instances an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice throughout the world, by or on behalf of the United States or by any foreign government pursuant to any treaty or other agreement with the Government of the United States, or for the Government for governmental purposes, of each such invention which results from performance of such contract.

(c) Acquisition of the rights specified in subsection (b) of this section shall be deemed sufficient in all cases for the protection of the public interest, so that additional rights shall not be required by any executive department or agency except upon certification by the head of such executive department or agency with respect to particular inventions that such additional rights are required under section 6 hereof.

(d) The acquisition of a proprietary interest greater than that set forth in subsection (b) of this section by the Government to an invention shall be subject to the reservation of an irrevocable worldwide, nonexclusive, royalty-free license to the contractor and to its existing and future associated and affiliated companies, if any, which license shall be assignable to the successor of that part of the contractor's business to which such invention pertains.

(e) Subject to the provisions of subsection (b) of this section, an executive department or agency may, whenever a contract provides for the taking of rights to an invention by the United States under subsection (a) of this section, waive the rights of the United States to such invention at any time on such terms and conditions as may be determined to be in the best interests of the United States. Waiver shall be granted under the following criteria:

(1) where the contractor has had substantial experience and background in the field of technology to which the invention pertains and the invention would have been a probable result of acquired skill or experience;

(2) where the invention is a natural adjunct to other inventions, the patents for which are owned by the contractor, and which in the course of time would probably have been developed by the contractor;

(3) where the invention is of such character that its commercialization would depend upon speculative investment to a substantial degree of a kind ordinarily facilitated by patent protection;

(4) where the invention has resulted from the continuation of development work in which the contractor has invested amounts which are substantial in comparison to amounts allocated to such development by the Government under the contract; or

(5) the invention has been developed by a small business concern, within the meaning of section 3 of the Small Business Act, whose economic welfare and competitive position would be enhanced through acquisition of title to the invention.

The granting of a waiver by an executive department or agency shall be accompanied by findings of fact made by the head of such executive department or agency, which desrcibe fully the basis under which the waiver was granted.

(f) Whenever the provisions of subsection (a) of this section require the head of an executive department or agency to take a proprietary interest in an invention greater than that specified in subsection (b) of this section, he shall take such greater interest unless he determines, after examination of the facts of the particular case, that special circumstances indicate that the contractor should receive all right, title, and interest in and to the invention, subject to the proprietary interest reserved to the United States in subsection (b) of this section, and that the public health, safety or security would not be affected adversely as a result of the contractor receiving said right, title and interest. The criteria for making this determination shall be—

(1) that the interest of the particular executive department or agency will not be adversely affected;

(2) that the interests of other executive departments or agencies of the Government will not be adversely affected;

(3) that there is a present commercial value and potential public use for the invention; and

(4) that the developer of the invention can reasonably satisfy public demand for and use of the invention.

Prior to making this determination, the head of the executive department or agency shall make findings of fact thereof. These findings of fact shall be communicated to the heads of other executive departments or agencies whose interests may be affected by the determination. The responses of such other executive departments or agencies shall be considered by the head of the executive department or agency concerned when its determination is made.

FURNISHING OF INFORMATION

SEC. 4. (a) Any party entering into a contract under section 3 hereof shall furnish to the appropriate executive department or agency a written report which shall detail full and complete technical information concerning any invention, discovery, or improvement made in performance of such contract, in accordance with such rules and regulations as the executive department or agency may prescribe.

(b) Any patent which issues to a contractor on an invention developed in the performance of a contract shall become the property of the United States and the patent be dedicated to the public, if upon a finding made pursuant to subsection (c) of section 6, and in the event an appeal therefrom is taken, such finding is affirmed by a proceeding brought under section 7 hereof, that the contractor knowingly and willfully withheld reporting of the invention required by an applicable contract.

LICENSING OF PATENTS

SEC. 5. Whenever the Government takes a proprietary interest in an invention greater than that specified in subsection (b) of section 3 and makes available to the public use thereof, the Government shall grant to the contractor which produced the invention an irrevocable exclusive, royalty-free license for practice of said invention if within three years of the taking of such interest by the Government, no actual use is made of said invention by another party. Such license shall be granted upon application by the contractor to the pertinent executive department or agency.

ADMINISTRATIVE PROCEDURE FOR DETERMINATIONS

SEC. 6. (a) Whenever the head of an executive department or agency shall determine that an invention, made in the performance of an obligation arising from a contract where the United States has taken rights no greater than those specified in subsection (b) of section 3, has given rise to new, unusual, and compelling factors related directly to the public health, safety, or security which did not exist at the time the contract was negotiated, but which require reconsideration of the rights established under said contract, he shall within sixty days after receipt of the information on which that belief is based—

(1) make a determination supported by findings of fact that he shall take on behalf of the United States a proprietary interest greater than that speci-

fied in subsection (b) of section 3 pursuant to the provisions of subsection (a) of section 3, or that he shall take no greater rights than are required by subsection (b) of section 3 because the invention does not come within any of the categories enumerated in subsection (a) of section 3. Such determination shall be based upon that criteria enumerated in section 3 (a) and (e) hereof; and

(2) if the executive department or agency head determines to take on behalf of the United States a proprietary interest greater than that provided in subsection (b) of section 3, he shall transmit to the contractor written notice of his intention, which notice shall—

(A) specify the nature of the proprietary interest in that invention which the executive department or agency head claims on behalf of the United States;

(B) state with particularity the basis for belief that the United States is entitled under this Act to take such interest in that invention; and

(C) accord to the contractor, or his duly authorized representative, an opportunity for a hearing, conducted pursuant to the provisions of subsection (c) of this section upon the question whether the United States is entitled under this Act to take such proprietary interest in that invention.

(b) If no application for a hearing is made by the contractor, or any other interested party, within sixty days after receipt of notice by the contractor, or if the executive department or agency head determines upon the record of any such hearing that the United States is entitled under this Act to take a proprietary interest greater than that provided in subsection (b) of section 3, the executive department or agency head shall issue with respect to that invention a written declaration of taking on behalf of the United States which shall—

(1) identify with particularity the invention to which it relates; and

(2) specify the nature of the proprietary interest therein so taken on behalf of the United States. Such declaration shall be served upon the contractor or upon his duly authorized representative, and a copy thereof shall be transmitted to the Commissioner of Patents. The executive department or agency head shall advise the Commissioner of Patents promptly concerning the pendency and result of any judicial review of such declaration.

(c) Whenever any section of this Act provides for a hearing to be conducted by an executive department or agency into the question of the proprietary of any determination made thereunder, there shall be issued to the parties involved a notice of intention to hold a hearing not less than sixty days after the mailing of such notice. Any hearing held under this subsection shall be conducted in conformity with the provisions of the Administrative Procedure Act. There shall be a right of judicial review under section 7 of this Act to any decision by an executive department or agency under this subsection.

JUDICIAL REVIEW

SEC. 7. Any person aggrieved by any declaration under sections 4, 5, and 6 may, under the Federal Rules of Civil Procedure, title 28, United States Code, obtain a review of such determination in the United States Court of Appeals for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides by filing an application for such review within sixty days after notice of such declaration or determnation. Findings of fact made in the administrative proceeding, if supported by substantial evidence, shall be conclusive. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

RIGHTS BY IMPLICATION

SEC. 8. No rights granted under any invention or patent pursuant to section 3 or section 5 hereof shall be deemed to grant any rights by implication under any other invention or patent.

GOVERNMENT PATENT PROTECTION AND USE

SEC. 9. (a) Whenever proprietary rights specified under subsection (a) of section 3 are taken to an invention by and in behalf of the United States through a declaration of taking, the head of the executive department or agency involved

ators and developers of technology will be an increasingly important factor in this growing international competitive struggle. If the representatives of American industry are to have maximum leverage in this struggle, it is important that they not be deprived of the asset of patent protection in foreign countries.

For these reasons I believe that, almost without regard to the allocation of U.S. rights in contract-connected inventions, disposition of foreign rights should normally be left in the hands of private contractors. Necessary safeguards in terms of compulsory licensing in situations involving essential international interests of the U.S. Government could readily be provided for.

I believe that with revisions related to the above suggestions, S. 1809 would well serve the public interest of the United States. I endorse the balanced and flexible approach which S. 1809 represents and hope for its enactment into law.

We appreciate this opportunity to express our views on this subject. If we can aid the subcommittee in pursuing this matter further we would be pleased to do so.

Sincerely yours,

FRANCIS K. MCCUNE, *Vice President.*

HAZELTINE CORP.,
Little Neck, N.Y., July 1, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks and Copyrights,
U.S. Senate, Washington, D. C.

DEAR SENATOR MCCLELLAN: For years we have anxiously listened to the intense debates on Government patent policy which have culminated in S. 789 (Saltonstall), S. 1809 (McClellan), and S. 1899 (Long), now before your committee. We think it imperative that the issue be brought to an early conclusion in order that the harmful uncertainty in industry be ended.

Before commenting on the three bills, permit us to outline our philosophy.

To us it is erroneous to assume that because the Government expends funds in research and development contracts with us, it is the father of resulting inventions. Such inventions are the outgrowth of our 40-odd years' accumulation of skills, experience, and investment in electronics, a field in which we are an acknowledged leader. We think it quite fair that our Government partner receive a nonexclusive license, but no more, because the intellectual property is basically ours—the creation of the brainpower of our skilled technical staff, which we alone train, support, and encourage with private risk capital.

All agree with the Government's desire to have inventions put to actual use. After all, that is the purpose of the patent system. But we believe this can best be accomplished by preserving our freedom to exploit for profit inventions which are, in any event, our own creation. As prudent managers of our stockholders' interests, we are very reluctant to risk capital in developing an invention if we do not have the shield of patents unhampered by fear of Government seizure. True, we will do it without patents if the gamble is a good one, but we will do it more, often with unencumbered patents. And make no mistake about it—considerable risk is involved in further research, product development, and marketing, after an invention is made, to put the invention in use by the public. We do not believe you are going to find businessmen as eager to take these risks where the patents are in a Government portfolio.

The history of our company is very much germane to the subject. Professor Hazeltine left Government service at the end of World War I with an idea on how to apply defense technology to the then-embryonic domestic radio receiver market. The company was formed around him and grew to its present size in the intervening years, during which it contributed extensively to the commercialization of domestic radio, monochrome, television, and, finally, color television. Out of this grew extensive contributions to defense electronics. Patents were an extremely important part of the business; it is quite probable that it never would have developed without them.

Despite what Senator Long is said to have testified, the patents, in practical effect, were the result of many millions of dollars of Hazeltine's own risk capital, not the Government's. Senator Long obviously does not have the facts. Of our present portfolio of about 500 U.S. patents, very few were the offshoot of work under Government contracts and only because our people were able to use our prior skills in the Government projects. Of the latter, none played any substan-

(e) The Saline Water Conversion Act of 1961 (75 Stat. 628) is amended by striking out section 4(b).

(f) The Coal Research and Development Act of 1960 (74 Stat. 336) is amended by striking out section 6.

(g) Section 4 of the Helium Act, as amended by the Helium Act Amendments of 1960 (74 Stat. 918) is amended by striking out the following language: "*Provided, however*, That all research contracted for, sponsored, cosponsored, or authorized under authority of this Act shall be provided for in such a manner that all information, uses, products, processes, patents, and other developments resulting from such research developed by Government expenditure will (with such exceptions and limitations, if any, as the Secretary may find it to be necessary in the interest of national defense) be available to the general public.

(h) The Arms Control and Disarmament Act of 1961 (75 Stat. 631) is amended by striking out section 32.

(i) The Water Resources Research Act of 1964 (78 Stat. 329) is amended by striking out section 303.

(j) The Appalachian Regional Development Act of 1965 (79 Stat. 20) is amended by striking out section 302(d).

EFFECTIVE DATE

SEC. 14. This Act shall take effect on the first day of the fourth month beginning after the date of enactment of this Act.

UNIVERSITY OF DENVER,
DENVER RESEARCH INSTITUTE,
Denver, Colo., June 8, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: I should like to submit for the record a brief statement of my personal views on S. 1809 and S. 1899 concerning Federal patent policy on which your subcommittee held hearings last week.

In summary, I favor, with a few exceptions, the terms of the chairman's bill, S. 1809, and oppose the terms of Senator Long's bill, S. 1899.

For 10 years, my applied economic and management research work has required frequent and intimate contacts with industry. During the last 5 years, the bulk of these contacts have been with technically oriented firms nationwide. The problems of Federal patent policy have entered into many aspects of this research work (which has been sponsored both by Federal and private funds).

This experience, plus study of the extensive hearings and publications on the subject of patent rights arising from federally sponsored contract research, have led me to conclude that with a few exceptions, patent rights should rest with private industry or should be made available on a limited-exclusive basis to private industry. Hence, my views are largely in agreement with S. 1809.

Proponents of the opposite viewpoint make very appealing arguments about the merits of a Government title policy such as advocated in S. 1899. Almost none of these arguments stands the test of scrutiny, in my opinion. For example, the argument is made that the Federal Government should take title to all patents arising out of research supported by the taxpayers to protect the public interest from "giveaways." But, rather than protecting the public interest, I believe a Government title policy harms the public interest by discouraging the commercial application of the fruits of the public's R. & D. tax dollars—thus tending to deny the public new, better, or less expensive products. I have been convinced of the validity of industry's argument in this regard. Since industry usually has to invest 10 or more times the R. & D. cost of an invention in designing, producing, and marketing it, there is a greatly reduced incentive to invest large sums to develop inventions on which the patent rights are nonexclusive.

Returning to the chairman's bill, S. 1809, I feel certain that my few objections to this bill were covered in detail in testimony made to your subcommittee last week. I only wish to state my belief in the generality that the more remote the Federal Government can place itself in such administrative matters as selecting licensees and protecting licenses from infringement, the better. Such activities

Our investments in research and development have averaged almost $1 million per year since the founding of the company and are currently running at over $2 million per year. Practically all of this R. & D. investment has come out of company funds without Government support.

Our company is a pioneer in the practical commercial application of atomic energy to peaceful industrial uses. We design, manufacture, sell and service a large family of precision radiation gaging and control systems especially adapted to meet widely varying requirements of the material-processing industries. We have installed well over 7,000 gaging and control systems, employing radioisotopes, in such basic material-processing industries as rubber, paper, plastics, tobacco, steel, and chemicals. Our products, sold under the trademark "AccuRay," combine principles of nuclear physics, advanced electronics and servomechanism theory to provide extremely precise measurement and control of moving materials being processed or chemicals flowing in pipes without contacting or touching the materials being processed. For example, some of our gages measure the thickness variations in extremely thin, plastic sheets, such as are used for food wrapping and packaging, and control the sheet profile to tolerances measured in microinches at commercial process speeds. Others of our systems precisely control the sheet thickness of heavy steel sheet traveling at hundreds of feet per minute and almost instantly detect abnormalities that might cause severe damage to the steel-rolling equipment. Others of our gages measure densities of liquid or dry chemicals in pipes with accuracies of better than 1 percent or precisely determine the fill-level of materials in bottles or cans on high-speed conveyor lines.

All this has been made possible by utilizing radioisotopes made available by the AEC for commercial uses, without significant Government financing or support. In fact, the Government has only recently come to our company to take advantage of our technology developed at our private expense.

Patents have played an important part in protecting our substantial private R. & D. investment. Our U.S. patent portfolio hos now grown to about 120 issued patents with over 100 patent applications pending. Accordingly, our company is very much concerned with Government policy and administrative procedures concerning rights to inventions developed under Government contract. We would like to help Government agencies make use of our know-how but, under the widely varying policies and procedures of various Government agencies, we find it difficult to assure that our commercial rights in our patents and technical data will not thereby be jeopardized. We have particular difficulty in dealing with the AEC because of statutory requirements and the AEC's restrictive patent and data policies. These problems are also present, in varying degrees, in dealing with the National Aeronautics and Space Agency, the Federal Aviation Agency and various branches of the Department of Defense. Some of these problems cannot at present be completely resolved by the individual Government agency because of statutory requirements; others are created by nonstatutory departmental policies. We hope that a few specific examples of recent problems in dealing with these Government agencies with respect to inventions and technical data will serve to point up the need for a more effective, though flexible, Government patent policy which will help us in dealing with any Government agencies who may seek our services.

PRESENT PRACTICES OF VARIOUS GOVERNMENT AGENCIES ON PATENT RIGHTS

You are intimately familiar with the present diversity in practice of the Government agencies and departments with regard to patent rights. It would appear helpful, however, to review briefly these practices to see how they affect a company in the position of Industrial Nucleonics Corp. which is particularly interested in developments relating to atomic energy and has acquired special capabilities in this field, almost entirely without sponsorship by the U.S. Government.

Industrial Nucleonics Corp. has had an unusual opportunity to experience in actual situations the current attitudes and practices of various Government agencies on patent rights. In fact, within the past 2 years, Industrial Nucleonics has negotiated with each of the Navy, Air Force, NASA, and the AEC, and contracts have been obtained from these agencies or departments. I will refer to specific examples of the practice of these departments by using the actual lan-

able for such purposes and I know of no Government agency whose mandate it is to get drugs through FDA approval. If there are any instances where a Government agency has in fact accomplished this, such an occasion must be so rare as to represent the exception that proves the rule that in this country virtually all of the drugs presently employed were brought to the patient and the physician through a pharmaceutical company.

Suppose some of the basic research leading to a potentially useful drug is accomplished in a university under partial or even complete NIH subsidy. The distance between that discovery and the ultimate approval of the drug by the FDA must be measured in years and in hundreds of thousands or in millions of dollars. Would a pharmaceutical company ever take that financial risk without having some assurance of protection for at least a certain period of time?

My own feeling is that, under such conditions, such a company should be given a semiexclusive license (the other partner obviously being the Government, which should retain rights to such an invention) for at least 6-8 years, starting from the date that FDA approval had been granted. There is a very good reason for that proviso. If, for instance, the invention dealt with a machine, a company could estimate the potential market, the size of its own investment required to bring the product to the market, and the chances of recovering its investment and of ultimately making a profit. This is clearly not the case with a drug. Some of the most promising drugs fell by the wayside after several years of extensive clinical testing. Furthermore, the less there is known about a given clinical use and the less precedence there is for similar drugs in that area, the longer it takes the FDA to grant approval—and properly so. I myself have been the discoverer or codiscoverer of a number of important drugs which are now used clinically. In two instances—the first antihistamine and one of the first oral contraceptives—no similar drug existed anywhere on the market and a great deal of extra work had to be done to convince the FDA of the safety and efficacy of such drugs. In the case of the oral contraceptive, the time interval between my initial chemical discovery (while working at Syntex) and the FDA approval was 10 years, 6 of which were spent solely on clinical work. There simply must be some protection to the company for the risk it assumes. If there will be no protection, then, in my opinion, the net result of section 4(a)(2) will be that very few if any potential drug discoveries made in universities under either partial or complete Government support will reach the public.

3. The definitions of "inventions made" in sections 2(e) and (g) are somewhat vague, at least in the area of drug research. According to the present operation of the Patent Office, a discovery is considered patentable only when a utility has been demonstrated. In a drug, such utility is its biological activity or the fact that the substance can be transformed into another one with biological activity. Who is the inventor under the definition in your bill? The person who first made the substance, or the one who discovered its utility? The drug field is replete with examples of the following type:

Frequently a chemist will synthesize a substance in connection with research that may have absolutely nothing to do with public health. The research work may have been completed months or years ago and then one day this substance is submitted to a pharmaceutical company for general pharmacological screening, which uncovers an interesting biological activity. Usually, further chemical modifications must be made (in this instance, probably in the drug firm's laboratory) before the best compound is obtained which can then be put through the laborious toxicological and clinical programs. Even if the very first compound submitted by the outside chemical investigator were the ideal one and required no further chemical modification, the complete biological, toxicological, and clinical work would still be required. Who is the inventor under your present bill? The chemist, who made the substance the first time, at a university under a Government research grant, but had no evidence of utility for it and hence could not patent it even if he wished to do so, or the pharmacologist in the drug firm who discovered the utility? How would such a case be handled?

The second and equally frequent occurrence is where the chemist has a very definite biological goal in mind when he first commences on his synthetic research. When the compound is finally tested, it is found to be inactive or toxic. However, when the same substance is screened for some completely different biological activity, it is found to be active. Again, who is the inventor?

I have described two extreme cases, but there are many others that fall in between. In each instance I have assumed that the pharmacological screening

in the taking of said rights may make application to the Commissioner of Patents for the issuance of a patent therefor to such executive department or agency head on behalf of the United States. If it is determined by the Commissioner of Patents that such invention is patentable, a patent shall issue to such executive department or agency head on behalf of the United States.

(b) Each executive department or agency head may grant a royalty-free, nonexclusive license for the practice of any invention for which a patent is held under this Act on behalf of the United States if such license is granted in furtherance of a purpose set forth in subsection (f) of section 3. If such nonexclusive license fails to result in the practice of an invention, such executive department or agency may thereafter grant an exclusive license subject to section 5 of this Act, provided a finding of fact is made by the head of such executive department or agency that an exclusive license is necessary to insure practice of the invention. Any party aggrieved by such finding of fact may bring proceedings under subsection (c) of section 6 of this Act. Any license under this subsection may be granted for the effective period of the patent or for a more limited period of time.

REPORTS TO THE CONGRESS

SEC. 10. The head of each executive department or agency which awards any contracts of the class described in section 3 shall submit semiannual reports to the Congress which contain—

(1) the number of inventions disclosed pursuant to such contracts;

(2) the number and general nature of such inventions with respect to which the executive department or agency acquired no greater right than those specified in subsection (b) of section 3, and a summary of the findings of fact upon which such determinations were made;

(3) the number and general nature of inventions coming under the categories described in subsection (e) of section 3 with respect to which no rights greater than those specified under subsection (b) of section 3 have been taken, and a summary of the findings of fact upon which such determinations were made; and

(4) the number and general nature of such inventions in which the executive department or agency has acquired a proprietary interest greater than a royalty-free license.

RULES AND REGULATIONS

SEC. 11. The Secretary of Commerce shall promulgate rules and regulations for the administration of this Act. Each executive department and agency of the Government may issue supplemental rules and regulations required for its internal administration and consistent with the rules and regulations promulgated by the Secretary of Commerce.

SEVERABILITY CLAUSE

SEC. 12. If any provision of this Act, or the application of such provision to any person or circumstance, is held invalid, the remainder of this Act or the application of such provisions to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

TECHNICAL AMENDMENTS

SEC. 13. (a) The Atomic Energy Act of 1954 is amended by striking out section 152 thereof (42 U.S.C. 2182).

(b) The National Aeronautics and Space Act of 1958 is amended by striking out sections 305 and 306 thereof (42 U.S.C. 2457, 2458).

(c) The National Science Foundation Act of 1950 is amended by striking out section 12 thereof (42 U.S.C. 1871).

(d) Section 10(a) of the Act of June 29, 1935, as added by section 101 of the Act of August 14, 1946 (60 Stat. 1085), as amended; 7 United States Code 427i(a) is amended by striking out the following language: "Any contracts made pursuant to this authority shall contain requirements making the results of research and investigations available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine."

not be the subject of patent applications or patents benefiting the investigator or the institution. Having stated these two premises, I would now like to point out that the present patent policy is probably unenforceable in its current form and that it can be pernicious if taken literally. Theoretically and legally, this will enable the Surgeon General to terminate most research grants at will if all administrative procedures are not followed by grantees, since he now has this prerogative. I shall demonstrate below with a concrete experiment that the majority of investigators are definitely violating the patent procedure as it is now defined and that they will be forced to continue to do so, because it is completely impractical. I shall also show that, even if the grantees followed the present regulations literally, the NIH would be in no position to handle the problem.

I am presuming that the chief purpose of the NIH grant program is the development of new knowledge and new capabilities in the health sciences and that such information should be made available to the public. The traditional and proper way of making it public is through the medium of scientific publication. I am assuming, further, that it is not the primary or even secondary function of the NIH grant program to secure patents on behalf of the Government. Indeed, in the relatively few cases where patents are taken out by the Government, they are made available on a royalty-free basis, thus fulfilling the concept of availability to the public.

Therefore, the only possible justification for patents is to safeguard the public from private individuals or organizations securing patents on the basis of earlier publications describing NIH-supported work, since such patent applications could be filed within a year of the publication date, provided certain other conditions were met. I imagine that occasionally such a situation may have arisen in the past and it is conceivable that it might arise in the future. However, if we consider the fact that there are well over 10,000 NIH grants in operation per year and that they give rise to probably a larger number of publications, it is false economy in the extreme to devise a system which will cost us untold millions of dollars in man-years to plug a possible minute loophole. The reason for my concern, and for my having performed the specific experiment outlined below, is the following:

Paragraph 52.22 (inventions and discoveries) as published in the Federal Register is covered in further detail in section 505 of the Grants Manual dated January 1, 1963. The first sentence of section 505, paragraph A, reads: "Department of Health, Education, and Welfare regulations (45 CFR, pts. 6 and 8) provide as a condition that all inventions arising out of the activities assisted by Public Health Service grants and awards *shall be promptly and fully reported to the Surgeon General.*" [Emphasis supplied.]

This report, according to paragraph C, must take the following form:

"C. FORMAL REPORTS OF INVENTION

"In respect to inventions reported direct to the Surgeon General for determination under Department regulations, a formal report of invention is required in the nature of answers to 18 questions listed in the outline for invention reports (exhibit 2). The form and other specific instructions for submission of the report will be provided upon request.

"Progress reports, which may include descriptions of inventions, may not substitute for formal reports of inventions."

In other words, in order to prevent the slight possibility that some other investigator may patent work performed by an NIH grantee, all possible discoveries or inventions should be reported to the Surgeon General, who will then decide whether patents should be taken out. If 10,000 to 20,000 publications are produced each year out of NIH-supported projects, the possibility then exists that the Surgeon General may wish to protect several thousand or perhaps all of them by patents. In order to be able to decide on this point, he must first have the necessary invention disclosures, which cannot be the usual annual reports of work performed under such grants.

NIH form PHS 3945 (dated March 1962, and now included in every new grant application form) defines an invention in the very broadest terms. In fact, these terms are so broad that, if the criterion of patentability is not left open to the individual investigator, a completely preposterous situation must arise. I shall cite one specific example: According to the present regulations, any invention or discovery (within the broad definition of PHS 3945)

would appear to present the Federal Government with many distasteful and difficult decisions which would be better left to the private sector if appropriate mechanisms can be developed.

Sincerely,

JOHN G. WELLES,
Head, Industrial Economics Division.

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., August 30, 1965.

Hon. JOHN L. MCCLELLAN,
Senate Subcommittee on Patents,
U.S. Senate, Washington, D.C.

MY DEAR SENATOR MCCLELLAN: I hope that it is not yet too late to send you some comments on your proposed bill, S. 1809. Unfortunately, the complete text of this bill reached me only recently. I am sure that you have received numerous communications on the subject and I would like to limit myself to only three points which have some bearing on my professional competence. As a university professor, I have published several books and well over 500 scientific articles in the field of organic chemistry, largely on health-related subjects, and over half of this work has been supported partly or completely by grants from two Government agencies (National Institutes of Health and the National Science Foundation). I have also had, and still have, intimate connections with the pharmaceutical industry—having been a research chemist or director in two such companies prior to my academic career, and currently serving on the board of directors of one of these (Syntex Corp.). However, none of my university research is currently being performed in collaboration with any pharmaceutical company.

On the whole, I am very favorably impressed with your bill and am largely in agreement with what you are trying to accomplish. There are three points, however, where I believe that modifications will strengthen the bill and be of ultimate advantage to the public.

1. You draw no distinction between contracts and research grants. In universities, and especially in health-related areas, virtually all of the Government support is obtained in the form of grants rather than contracts. In section 3 (b) (1), your bill requires "the prompt and full disclosure by the contractor to that agency of any invention made in the course of or under the contract."

The NIH has already been operating theoretically under this assumption under their revised patent policy. In connection with its publication in the Federal Register, I wrote to the Surgeon General on July 24, 1963, indicating that such a requirement is totally unrealistic since it cannot be complied with and cannot be enforced. Many of the comments in that letter (especially pp. 2–4), of which I am enclosing a copy, also apply to section 3(b) (1) of your bill (every university scientist working under partial Government support is a "contractor") and I believe that an appropriate modification in the wording should be considered. Other than acknowledging receipt of that letter, I never did receive any reply from the Surgeon General. Senator Wayne Morse, with whom I once had some personal discussion during a plane trip on the general subject of Government support of academic research, had this letter and some related material republished in the Congressional Record (August 6, 1963, pp. 13434–13440, and especially pp. 13439–13440).

2. In section 4(a) (2), your bill reserves principal or exclusive rights to the Government in any invention made in the field of public health. While I sympathize with the motive, the result of this clause—if permitted to remain—will have precisely the opposite effect in that it will be to the disadvantage of the taxpaying public. I am making his rather blunt statement for the following reasons.

To my knowledge, during the past 10 years probably not a single important drug has been developed in an American Government or university laboratory and brought to approved human use through the FDA by such an agency or university. Under present FDA regulations (with which I agree), the possibility of such an event happening becomes virtually zero. I would estimate that, in the case of a new drug, it would cost an absolute minimum of half a million dollars, and frequently several millions, to satisfy all the FDA requirements for human use and for manufacture. No university has such money avail-

by some uninformed individual, because it is poor administration and ineffective procedure to have a regulation on the books which no one can follow. The only purpose I can see in it is that it now gives the Surgeon General a means of terminating a grant in "midair" by pointing out that a grantee has not followed an administrative regulation.

I recommend that the patent policy be simplified and adapted to the de facto situation:

(*a*) No patents are to be filed by any NIH grantee unless he proceeds in the manner outlined in the present patent policy (sec. 505(par. A).

(*b*) But, if the NIH grantee does not intend to file a patent application, no specific report should be required of him, his annual progress report and the eventual publications representing sufficient evidence that he has complied with the spirit in which the grant was made.

Yours sincerely,

CARL DJERASSI, *Professor of Chemistry.*

STATEMENT OF ROBERT C. ELDERFIELD

Mr. Chairman and distinguished members of the subcommittee, my name is Robert C. Elderfield and I appear before you today solely as an individual vitally interested in the future applications of such discoveries and inventions as may be forthcoming from our scientific and technological community to the general welfare of the people of the United States.

I am a professor of chemistry at the University of Michigan, a member of the National Academy of Sciences, a former chairman of the Division of Chemistry and Chemical Technology of the National Research Council-National Academy of Sciences, a member of the Board of Directors of the American Chemical Society and chairman of the American Chemical Society Board Committees on Education and Students, Grants and Fellowships, and International Activities. In the past I have served on various advisory panels and committees of the National Institutes of Health and am presently serving on three advisory boards to the Department of the Army. I am the author or coauthor of some 200 scientific papers and the holder of some 14 patents assigned to both private industry and various agencies of the Government. I have no connection with any industrial organization interested in the pending legislation.

Three bills are before your committee for consideration: S. 1899, introduced by Senator Long; S. 1809, introduced by Senator McClellan; and S. 789, introduced by Senator Saltonstall. I understand a fourth bill, S. 2326, introduced by Senator Dirksen, may also be considered by the subcommittee. While I have not studied this bill in detail, it appears to be in line with the philosophy expressed in my statement.

Previous testimony has amply documented the arguments against S. 1899 and I do not propose to belabor these. I intend, therefore, to confine my remarks to S. 1809 and S. 789. Furthermore, I shall limit my remarks to the application of the results of fundamental research subsidized in whole or in part by Federal funds in the universities of the country to the general benefit of the people of the United States.

Previous witnesses before you have emphasized the cost and the financial risks involved in the reduction of a laboratory "discovery or invention" to practice or, in other words, "development costs" in relation to "research costs." I should like to explore this phase of the problem a bit further with particular emphasis on matters affecting the public health, welfare, and safety of the American people. I believe that a strong case can be made for the argument that cooperation between university scientists and industry is capable of returning high yields for the benefit of the public in these areas.

Let us consider briefly the history of chloramphenicol ("Chloromycetin") as a prime example of the fruits of university-industry collaboration with resultant tremendous benefits to mankind. This material is one of the major antibiotics useful in treatment of typhoid fever, typhus, undulant fever, and many other infections. In 1947, Paul Burkholder, then professor of microbiology at Yale University, working under a pharmaceutical company grant, collected a soil sample in Venezuela, cultured this material, and sent it to the company for further testing. The powerful therapeutic activity of the antibiotic constituent was then discovered. This was followed by extensive development work at the

is done by a drug firm. This assumption is well founded, being based on my years of academic research where I was interested in having certain substances exposed to a wide pharmacological screening and found no Government or university laboratory equipped to do so. I still remember filing an NIH application more than 10 years ago on natural products from South American plants where the NIH study section inquired where the biological screening would be done. I indicated that I planned to send the substances to various drug firms such as Eli Lilly (a company with whom I had no formal connection whatsoever at that time, not even as a consultant) and this reply was considered entirely satisfactory by the NIH at that time. If I were to attempt to do this now, I would probably encounter great difficulty in locating any firm that would be interested in carrying out such screening.

Why can such screening not be done in university laboratories? It is possible to find investigators in pharmacology departments of certain medical schools who might be interested in testing compounds for a very specific type of biological action that they happen to be interested in, but I know of no such department in the United States or elsewhere where a broad biological screening for a wide variety of activities is performed. In fact, many of the best pharmacology departments in medical schools consider such work beneath them and are much more interested in studying the mechanism of action of known drugs or actually performing biochemical research. There is nothing wrong with this, since such work is very important, but it does not answer the question of where such screening can be performed in a university.

What about Government laboratories? Again, screening for certain activities can be done in certain Government laboratories, but general pharmacological screening for all types of potentially interesting biological and bacteriological activities is not available in any Government laboratory. If it were, I would be very interested to learn of it. About 10 years ago, while I was a professor at Wayne State University, I submitted various compounds to the NIH for testing in certain hormone assays (a specialized and very limited type of activity) and some of the results have come in to me only during the last 2 years. Frankly, I had already forgotten that I had ever submitted these substances. I am not citing this example as a criticism of the NIH. On the contrary, the NIH is fulfilling its real mandate very effectively and is playing an absolutely indispensable role in supporting most of the health-related basic research in American universities. Furthermore, a great deal of high-caliber intramural research is also being performed by scientists at the NIH. General pharmacological screening, however, is not one of the functions of the NIH and consequently is not done there to any extent, at least as far as I or many of my university colleagues are aware.

I have the impression that the new NIH patent regulations have virtually dried up this type of collaborative research between academic chemists and the pharmacological laboratories of drug firms. I believe that this is a pity, because there is little doubt that worthwhile drugs come out of such collaboration and that the one who suffers ultimately is the patient. The present provision (sec. 4(a)(2)) of S. 1809 is unlikely to change this state of affairs.

Yours sincerely,

CARL DJERASSI, *Professor of Chemistry.*

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., July 24, 1963.

Dr. LUTHER TERRY,
Surgeon General, Department of Health, Education, and Welfare, U.S. Public Health Service, Bethesda, Md.

DEAR DR. TERRY: In your memorandum of June 12, 1963, addressed to all NIH grantees, you invited views and comments on the proposed research project grant regulations which appeared in the Federal Register in early June. This letter encompasses both comments and criticism on the present patent policy and I trust that it reaches you before the expiration of the 60-day deadline.

At the outset, I wish to emphasize that I am discussing only research grants and not research contracts. Furthermore, I would like to state that I am in complete agreement with the basic premise of the NIH patent policy; namely, that inventions made under partial or total NIH grant support should

That section 4(a)2, which applies substantially the same restrictions to the area of "public health, welfare, and safety" as are contained throughout the Long bill (S. 1899), be modified so as to provide in positive language adequate incentive to restore the past most fruitful collaboration between the university scientists and industry which at present has largely vanished. Such action could not but be most effective in making available to the public at large the benefits accruing from the heavy investment of public funds in matters of public health, welfare, and safety.

Specifically I would suggest that a given pharmaceutical firm be granted an exclusive license under either NIH-owned patents or preferably patent rights released by the Government administration by the grantee universities themselves on a new agent for a mutually agreed on term of years for recognition of its considerable contribution to the research and development effort involved as well as for the risk of its private capital. In return the company should use its best efforts to make such an agent promptly available to the public at a reasonable cost commensurate with the firm's investment of capital, facilities, and know-how.

In discussing such a policy with my colleagues I find differences of opinion as to the duration of the exclusive license. A good bit depends on the base point. If the period is calculated from the time a given drug is available for the market I would think a period of the order of 5 years would accomplish the objective. If it is based on the date of issue of the patent possibly 10 years should be considered. The 10-year term seems reasonable if it is kept in mind that some 5 years normally elapse between the discovery of a new agent and its availability to the public. The new FDA rules alone require some 3 years of clinical experience with an agent under close surveillance prior to its approval.

The disposition of "offshoot" patents arising from efforts by the firm and financed exclusively by the firm during the course of the development work warrants consideration. My feeling is that these should remain the property of the firm.

Adequate safeguards to insure prompt performance of the development work and to protect the public from exhorbitant prices should be part of the licensing agreement. These are probably met by the "march-in" provisions of the bills as they stand.

It is also important that all contract arrangements be concluded or clearly understood in advance of any participation by a firm.

Senator Saltonstall's bill (S. 789) accomplishes essentially these objectives. However, I believe, as indicated above, that the 3 years allowed for placing a new product in commercial use as given in section 6 is too short and should be roughly doubled at least in the case of new therapeutic agents.

From 1959 to 1964 the number of major new chemicals introduced yearly as prescription drug products declined from 63 to 17. While during the same time the aggregate yearly research and development expenditures of the pharmaceutical industry increased from about 190 million to about 300 million. Clearly this portrays a dramatic picture of increased costs in research and development with a corresponding decline in major new product introductions and underscores the need for a reasonable degree of market exclusivity.

It has also been estimated that the time spent on developing just one new, efficient drug, if only one person were involved in all study and research, would require 19 working years or 58,000 hours of the worker's life. This work and the attendant expenses in many cases is completely lost if the safety and efficacy of the drug is not demonstrated to the complete satisfaction of the Food and Drug Administration.

I submit that merely an investment of this magnitude in development of a single drug which is covered by a Government-owned patent provides ample justification for limited exclusive privileges for a cooperating company without considering the high failure rate in the development of chemicals into useful drugs. The alternative is for Government to assume these development costs. Otherwise advances made possible by federally sponsored research will remain on laboratory shelves indefinitely.

In conclusion, I should like to express my appreciation for this opportunity of presenting my views.

must be reported immediately to the Surgeon General. When this is done, the investigator receives by return mail an outline for invention report, consisting of 18 questions and included as exhibit 2 in the Grants Manual. I personally have received such a questionnaire. If I were to answer it haphazardly, I could do so in half a day; if I were to answer it in a really proper manner, it would take several days. Only after the investigator has filled out this questionnaire and returned it to the NIH will the legal staff of the NIH decide whether this material is patentable, regardless of whether the investigator wishes to take out a patent or even whether he considers the material patentable.

I maintain that this procedure is not enforceable and would have preposterous consequences if any attempt were made to enforce it. Of the several thousand NIH grants, at least 50 percent are certain to contain some invention or discovery falling within the definition of NIH form PHS 3945. Many of the NIH grants will contain several such inventions or discoveries. Among the grants in chemistry or biochemistry, I would estimate that over 80 percent fall within this category. Any patent lawyer will confirm that the question of "patentability" is very difficult to answer and that the answer depends largely on one's attitude. If one is interested in securing a patent, a patent attorney can make a good case that a given subject is patentable, while the exact reverse can be accomplished if the attorney is trying to prove that a given subject is not patentable. One can estimate conservatively that, of all chemical patents issued yearly by the U.S. Patent Office, 50 to 70 percent would be declared invalid if carried through the courts—the reason being precisely the uncertainty which exists about the definition of a real invention. I wonder whether the Surgeon General is aware of the fact that many patent applications are filed and patents granted in the chemical and pharmaceutical areas that do not include any experimental work at all—all of the work on the invention or discovery being "paperwork" and that such patents are entirely legal under our present system.

With this information as background, I performed the following experiment: I selected at random only one issue of a chemical journal—the April 1963 issue of the Journal of Organic Chemistry—and then picked out all the articles which acknowledged NIH grant support. There were 17 such articles in the April issue. Of these, I could select only three (pp. 900, 1075, and 1086) which I could definitely say did not contain patentable material. In three other instances (pp. 936, 945, and 1128), an excellent case could be made for patentability, including a statement of utility. Of the remaining 11 articles, in 7 (pp. 923, 928, 942, 964, 1098, 1108, and 1119) a good case could be made for patentability and in 4 (pp. 1004, 1015, 1037, and 1041) a weak case.

According to the present NIH rules, 14 of these 17 investigators should have filed an invention record and subsequently answered the 18 questions of the outline for invention reports. Reckoned conservatively in man-hours, this would require 1 to 2 months. But the real work would start only when the NIH legal staff received these documents and started wading through them. I would estimate that this experiment would have to be multiplied at least several hundredfold each year to cover all relevant grants and that the NIH would require a legal staff which would have to be much larger than the examining staff of the U.S. Patent Office. It would also involve several hundred man-years of investigators' time to handle all the reports, answers, etc., and it should be remembered that the most productive investigators are those whith several collaborators, who very likely have many such invention reports each year at various stages of processing.

To complete the above-outlined small experiment from the April 1963 issue of the Journal of Organic Chemistry, I recommend that the Surgeon General put a member of his staff on the job of checking the 17 grants to determine whether any invention statements have been filed. The chances are excellent that he will find none. The chances are poor that he will find 2 or 3 and the probability is infinitesimal that he will find even 10—let alone the experimentally determined 14 which would be required.

Does this mean that all of these investigators are dishonest, that they are using NIH funds without fulfilling regulations, that they are filing patents surreptitiously? The answer is that the present patent policy is impractical and unenforceable because it cannot be practiced—either by the investigators (who would end up having little time for research if they followed literally the patent regulations) or by the NIH (which does not have even a fraction of the legal staff necessary to handle hundreds of such reports annually). I conclude, therefore, that the patent policy should be changed, before an uproar is raised

the contractor of title in such a case. Suppose, further, that a contractor has spent hundreds of thousands of dollars of his own money in developing an idea practically to reduction to practice and then uses it for the first time in connection with a $50,000 contract. The contractor could, perhaps, very easily have avoided using the idea but, wishing to cooperate to the maximum with the Government he has applied his best technology in order to give the agency involved the best possible solution to its problem. Is it fair in such a case that the contractor lose title? We believe not. Hence, we believe that subject inventions should be limited to conceptions. If, on review of this matter, it is believed that some reductions to practice should be included within the definition, we respectfully submit that exceptions should be made when suitable equities are present.

Referring to section 3(b)(5), the determination of reasonable terms and conditions and, perhaps, the grant of compulsory licenses is placed in the hands of the agency involved. It seems to us that it may be advantageous from the Government's standpoint as well as from the public benefit point of view that the agency head do no more than supervise the grant of the licenses or be available as a "referee." In this manner, the burden of negotiating licenses would be transferred from the agency head to the contractor in an area where we believe the contractor would be more than happy to assume the burden and where the agency head is usually not best able to determine fair terms and conditions. There is no such thing in the area of licensing of the use of standard terms and conditions except in very limited situations. There is no substitute for depth of experience in a field to appreciate what is fair and workable and what is not. For example, what is a fair rate of royalty? What is the proper base to which the rate is applied? Should it be the entire apparatus furnished or only the proportionate part covered by the invention? What should be done about information, grant backs of rights possessed by the licensee, and improvements? Should the licensee or the licensor be required to police the patent or patents involved? On what grounds should the licensee or licensor be permitted to terminate the agreement? Should the licensee have the right to grant sublicenses? Should the licensee be required to exercise his best efforts in connection with the subject matter in order to maintain the license? Should the license be exclusive or nonexclusive? In almost every situation, the decision must be made on a case-by-case basis.

Referring to section 3(b)(8), we note that there is no excuse whatsoever permitted for failing promptly and fully to report an invention. In view of the serious penalty, i.e., forfeiture, involved and because reasonable men can well differ on reasonable time for reporting as well as whether reporting is required, we would urge insertion of the words "in bad faith." In support of the above suggestion, it is noted that conceptions and first actual reductions to practice form the basis for reporting of inventions. As a quick glance through board of interference and court decisions on interference situations will disclose, it is often difficult to determine when a conception has been made and when an actual reduction to practice has been made. Many interferences and court cases hinge on these determinations and, since there is usually involved a question of judgment with respect to which attorneys will differ, it is believed that a sort of "rule of reason" should be applied in this area and that severe penalties should not be enforced unless an element of fraud is present.

Referring to section 4(a), and more particularly to the criteria identified as justifying the taking of principal rights, there are certain ambiguities or at least certain degrees of indefiniteness which, in our opinion, are likely to cause future problems.

Referring to subparagraph (1), it would seem to us of doubtful value for the Government to acquire title to all inventions made merely because the invention may be required for use by governmental regulations or the public may become a user. In this connection, we would distinguish, for example, between a contract having as an object an improvement or cost reduction or some other minor modification of a well-known drug such as aspirin as distinguished from research directed to a significantly important medical advance such as a cancer cure. The same approach is applicable to subparagraph (2) where you might distinguish between an improvement in stair treads to minimize the danger of slipping as compared with a device for absolutely preventing collisions between vehicles. To soften the impact on contractors without disadvantaging the public, both of

company as well as by investment of capital in the huge vats and other equipment necessary for the commercial production of a drug by fermentation and, of course, not available at most universities. Later the chemical structure and a chemical method for synthesizing chloramphenicol commercially were discovered at the company. Not only was this the first antibiotic produced by chemical methods rather than by fermentation, but the chemical work enabled the initial costs of preparing this lifesaving drug to be reduced greatly. This is a prime example of beneficial cooperation of university personnel with industry. If Dr. Burkholder had had a Government grant in 1947 and the restrictions of S. 1899 and S. 1809 in their present form were in force this very important therapeutic agent might not have been made available to the public.

Another example of university-industry collaboration can be found in the pioneering drug diphenhydramine ("Benadryl"). The chemical was prepared by an academic group at the University of Cincinnati under Dr. George Rieveschl and was sent to a pharmaceutical company for testing as an antispasmodic. During the general testing of the compound, its very potent antihistaminic activity was discovered. Today this drug is considered to be the "father" of the antihistamines and still one of the most potent and widely used of this class. Once again, a most unusual drug might have been lost without industry-university collaboration.

Literally tens of thousands of diabetics are alive today because of the availability of insulin, first discovered by Frederick Banting at the University of Toronto and made available to the public by collaboration with an American drughouse.

As one final example, one can cite the spectacularly impressive record of the so-called cortical hormones: ACTH isolated by Li at California; cortisone by Kendall at the Mayo Foundation, to mention two. Through industry collaboration not only these but improved drugs based on these early leads are now available for treatment of a host of diseases.

Turning to the present situation, which has arisen largely because of restrictions initiated by the National Institutes of Health, we find that collaboration between NIH grantees and industry has substantially ceased. Under these restrictions all property rights to a chemotherapeutic agent revert to NIH if any NIH funds, however small, are involved. Let us consider a couple of examples of the potential harm arising from such restrictions.

For the past few years with NIH support I have been interested in constituents of certain plants as possible therapeutic agents. Among others we have found a tree bark which contains a substance which, through collaboration with a pharmaceutical firm prior to 1963, we have found exerts a profound effect in lowering blood pressure in animals. So far we have not succeeded in separating the active substance from the other constituents of the bark largely because we have had no way of securing the necessary animal tests since 1963. The company in question, in common with practically all others, does not feel that it can sign the overly restrictive NIH patent agreements which must be executed by the company prior to the collaborative work.

A colleague of mine has on his shelf some 26 compounds synthesized with NIH support and specifically designed for treatment of hypertension and atherosclerosis. He is unable to get these screened by any pharmaceutical firm.

The shoe also fits on the other foot. The same colleague also has on his shelves 11 compounds synthesized for control of malaria (a very pressing problem now in southeast Asia due to development of resistance to the commonly used drugs). Support for the synthesis of these substances came from a pharmaceutical firm which naturally desires to retain rights to them but which has no facility for screening them for antimalarial action. Negotiations with NIH, which does have such facilities, for doing the screening, revealed that should NIH screen them all rights would revert to the Government.

Thus, collaboration in this vitally important area has been effectively blocked with resultant unfortunate effects, to say the least, on the general public health, welfare, and safety.

In the light of the preceding discussion, may I therefore suggest the following modification of the McClellan bill (S. 1809), which otherwise I consider an excellent bill, for your serious consideration in the public interest.

(d) The term "contractor" means any person and any public or private corporation, partnership, firm, association, institution, or other entity which is a party to the contract.

(e) The term "invention" means any invention, discovery, innovation, or improvement which appears to be reasonably patentable under title 35, United States Code.

(f) The term "disclosure" means a written statement sufficiently complete as to technical detail, *to the extent available,* to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation and, as the case may be, physical, chemical, or electrical characteristics of the invention.

(g) The term "made", when used in relation to any invention, means the conception ~~or first actual reduction to practice~~ of such invention ~~in the course of or~~ under the contract.

(h) The term "to bring to the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine or system and, in each case, under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

CONTRACT REQUIREMENTS

SEC. 3. (a) Whenever any Government agency enters into any contract where a *principal* purpose is the conduct by a person of *a significant degree of* experimental, development, or research work, there shall be included in that contract provisions determined, under regulations which shall be promulgated by the head of that agency, to be effective to carry into effect the requirements of this Act.

(b) Each contract entered into by any Government agency shall contain provisions effective to—

(1) require the prompt ~~and full~~ disclosure by the contractor to that agency of any invention made in the course of or under the contract;

(2) reserve to the United States not less than an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice throughout the world, by or on behalf of the United States or by a foreign government pursuant to any treaty or other agreement with the Government of the United States *in force at the time the contract is entered into,* of each such invention;

(3) reserve to the contractor not less than an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention *together with the right to grant sublicenses of the same scope to the extent the contractor was legally obligated to do so at the time the contract was awarded.* Such license shall extend to its existing and future associated and affiliated companies, if any, within the corporate structure of which the contractor is a part and shall be nontransferable, except that it shall be assignable to the successor of that part of the contractor's business to which such invention pertains;

(4) reserve to the United States such greater rights in each such invention as the head of that agency may determine in conformity with the provisions of this Act;

(5) provide, in the case of the issuance to any person other than the head of that agency of the principal or exclusive rights in any invention, appropriate means whereby such agency head thereafter may require the owner of those rights to grant to other persons licenses for the practice of such invention, upon such reasonable terms and conditions *subject to review by the agency head at the request of either party to the negotiation* ~~as the agency may prescribe~~ upon a determination made by such agency head, after affording the opportunity of a hearing to the owner of those rights, that (a) the owner of those rights has not *within three years after issuance of the patent* exerted substantial efforts to bring the invention to the point of practical application and (b) the public interest would be *better* served by *requiring the owner to license one or more* ~~the issuance to~~ other persons ~~of licenses for the~~ *to* practice ~~of~~ that invention;

(6) provide, in the event the principal ~~or exclusive~~ rights in any invention are acquired by the head of that agency on behalf of the United States, and such agency head does not *timely* elect to secure a patent in a foreign country, appropriate means whereby the contractor may *timely* file and retain such greater foreign rights, subject to the rights reserved to the United States in subsection (b)(2) of this section;

ELECTRONIC INDUSTRIES ASSOCIATION,
Washington, D.C., July 19, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: It is the purpose of this letter to supplement the statement transmitted to the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee in connection with the recent hearings relating to S. 789, S. 1809, S. 1899, and S. 1047. We hope that it will be helpful to your subcommittee if we supplement our prepared statement and add emphasis to matters raised by other witnesses at the hearings of June 1 and 2, and July 6 and 7.

We also have prepared a complete line-by-line recommendation for the convenience of your committee and staff. Since the line-by-line analysis of S. 1809 is all inclusive, regardless of relative importance, it is, so far as we are concerned, of no consequence that this additional paper become part of the record of the hearing of the subcommittee and it is offered only as a convenience.

There is one area where we would especially like to suggest thoughtful analysis. In testimony given on June 1, we heard discussions concerning the division of rights between the Government and between the contractors. In discussing the rights of Government, are we concerned with the right thing? Are we sometimes too close to the subject? Are the trees obscuring the forest?

The Government's needs, strictly speaking, have nothing to do with who holds title to an invention. Every Government need can be taken care of adequately with a license.

The public benefit is the key consideration and it does not follow automatically, in our opinion, that the public is best served when title is taken by the Government. We suggest that economic growth is our primary goal. New technology is very important to the achievement of that goal and many of us believe that that goal is reached best and fastest by leaving title, whenever possible, with the contractor who is responsible for the invention.

This is still a nation where the Government steps in only when non-Government can't or won't operate. The question was asked on the first day of the hearings, "Why does the contractor want title?" As a matter of law, title vests in an inventor or his assignee concurrently with the making of the invention. Hence, the contractor owns the invention upon its conception. Why does the Government want to deprive him of the invention? The Government does not take away the contractor's specially trained scientists. The contractor should retain title, under the principle stated above, unless there is a clear public interest superior to the contractor. Title in the contractor should therefor be disturbed as rarely as it is possible to do so. It can be argued that the public interest requires the taking of title only when the contractor won't or can't advance the technology.

A lot was said at the recent hearings about commercialization of inventions. We are sorry that so little was said of the importance of disclosure and yet disclosure is the primary purpose of the patent grant; i.e., the exchange of limited exclusivity for disclosure—not commercialization but disclosure. Some very valuable inventions may be commercially impracticable but they trigger off others which make commercialization feasible.

We wish to endorse the position taken at the hearings concerning the definition of "made" with respect to the making of an invention. The disposition of title to inventions should be based upon "conceptions" and should not sweep in reductions to practice. Industry was unhappy when the Department of Defense adopted this language years ago at a time when the Government received only a license and even then excluded the taking of such licenses when certain conditions were in existence. For example, suppose that modification is invented in electronic equipment. Its utility seems so obvious that the company involved does not rush to reduce it to practice or, perhaps, the inventor has tested the idea to his own satisfaction but has not yet demonstrated it and therefore has no corroboration. Now, suppose that a Government agency wishes to develop some apparatus and the invention previously conceived appears to be quite useful in fulfilling the work to be performed under the contract. Under section 4(a)(1), the contractor would lose title and yet the contractor has accomplished, at his own expense, everything except the final formal step. We do not believe that it is fair for the Government to deprive

In exceptional circumstances the determination of such rights may be made at the time of contacting, if the agency head certifies that such action will best serve the public interest.

ADMINISTRATIVE PROCEDURES FOR DETERMINATIONS

SEC. 5. (a) Whenever a contract provides the agency head with the right to acquire, after the invention has been identified, greater rights than the nonexclusive license specified in section 3(b)(2) and and he decides to exercise such rights, he shall within sixty days after receipt of the disclosure required by section 3(b)(1):

(1) make a determination supported by findings of fact, that he shall acquire on behalf of the United States greater rights than the nonexclusive license specified in section 3(b)(2) pursuant to the provisions of section 4(b) or section 4(c);

(2) if the agency head determines that he shall acquire on behalf of the United States greater rights than the nonexclusive license specified in section 3(b)(2), he shall within sixty days after making such determination transmit to the contractor written notice of his intention which notice shall—

(A) specify the nature of the property right in that invention which the agency head claims on behalf of the United States;

(B) state with particularity the basis for belief that the United States is entitled under this Act to acquire such property right in that invention; and

(C) accord to the contractor, or his duly authorized representative, an opportunity for a hearing, conducted in compliance with the provisions of the Administrative Procedure Act, upon the question whether the United States is entitled under this Act to acquire such property rights in that invention.

(b) If no application for a hearing under section 5(a)(2)(C) is made by the contractor, or his duly authorized representative, within thirty days after receipt of notice by the contractor, or if the agency head determines upon the record of any such hearing that the United States is entitled under this Act to acquire greater rights than the nonexclusive license specified in section 3(b)(2), the agency head shall issue with respect to that invention a written declaration of acquiring on behalf of the United States which shall—

(1) identify with particularity the invention to which it relates; and

(2) specify the nature of the property right therein so acquired on behalf of the United States. Such declaration shall be served upon the contractor or upon his duly authorized representative, and a copy thereof shall be transmitted to the Commissioner of Patents. The agency head shall advise the Commissioner of Patents promptly concerning the pendency and result of any judicial review of such declaration.

JUDICIAL REVIEW OF DETERMINATIONS

SEC. 6. (a) Whenever *an agency head acquires the principal rights under section 4(a), or* any such declaration of acquiring is issued by an agency head after hearing, or any final determination is made under section 3(b)(5) *or section 3(b)(8)*, any party aggrieved thereby shall be entitled to a judicial review of the basis for such declaration or final determination by filing a written petition for an order setting aside that declaration or determination in the United States Court of Appeals for the District of Columbia or in the court of appeals of the United States for the judicial circuit in which such party resides and serving a true copy of the petition upon the agency head, within sixty days after notice of such declaration or determination. The agency head thereupon shall certify and file in the court a true and correct transcript of the entire record of the proceedings upon which the *acquisition*, declaration or determination was based, including all evidence taken and the findings and conclusions made by the agency head thereon.

(b) The court shall have jurisdiction to hear and determine any such petition, and shall have power to affirm, modify, or set aside the *acquisition*, declaration or determination. In any such review, the findings of fact made by the agency head, if supported by substantial evidence, shall be conclusive. If either party shall

these criteria might be restricted to improvements or inventions of critical significance in connection with the end objective. These problems are particularly serious for would-be contractors in drug and safety fields.

In section 4(a)(3), the Government may acquire greater rights whenever the invention "might" confer on the contractor a "preferred or dominant position." It can be argued and has been argued under the present DOD regulations that every patent confers a preferred position. Indeed, this is the purpose of the grant of a patent. It is not this sort of preferred position which you have in mind, we are sure, and, similarly, others who have proposed this type of language have not had this kind of dominance in mind. Therefore, it is believed that it would be helpful to reword this criterion as follows: "rights at the time of contracting is likely to confer on the contractor a dominant position;".

With respect to section 8(b), we would urge that a careful study be made because, at first thought, it appears to be repugnant to argue that the public benefit requires the taking of exclusive rights from the contractor only to, in turn, pass on those exclusive rights to another citizen or U.S.-based firm. It is for this reason that many believe that any citizen who wishes to use a Government-held patent should be entitled to a free, nonexclusive license. Both Saltonstall and Long propose dedication. We believe this approach is sound in most cases. In those cases where exclusivity is necessary for development, we believe exclusivity should remain with the contractor. The public interest can amply be satisfied by compulsory licensing.

Referring to lines 10 and 11 on page 15, the license provided therein may be granted with or without the payment of royalty to the United States. This type of language can lead to governmental regulation of industry by determining who can have a license and how much he may have to pay. It has been advocated, for example, that the Government grant exclusive licenses to a small company to help it grow larger and then when it is large enough to stand on its own feet, the license should be taken away and given to someone else or the royalty rate should be increased or some other step taken to remove any advantage it might have. Many fear this type of Government entry into the control of the business of the Nation.

Very truly yours,

T. L. BOWES,
Chairman, EIA Patents and Proprietary Information Committee.
GRAHAM W. MCGOWAN,
General Counsel, Electronic Industries Association.

SUGGESTED AMENDMENTS TO S. 1809

[Omit the part struck through and insert the part printed in italic]

A BILL To establish a uniform national policy concerning property rights in inventions made through the expenditure of public funds, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Federal Inventions Act".

DEFINITIONS

SEC. 2. As used in this Act—

(a) The term "Government agency" includes any executive or military department of the United States, any other agency, independent commission, board, office, administration, or authority of the Government, and any wholly owned Government corporation.

(b) The term "agency head" means the head of any Government agency, except that (1) the Secretary of Defense shall be the agency head of the Department of Defense and of each military department thereof, and (2) in the case of any authority, commission, or other agency, control over which is exercised by more than one individual, such term means the body exercising such control.

(c) The term "contract" means any *written* contract, grant, agreement, commitment, understanding, or other *written* arrangement entered into between any Government agency and any other person where a *principal* purpose of the contract is the conduct of experimental, development, or research work. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract.

(b) Each agency head may grant an *appropriate* ~~exclusive or non-exclusive~~ license for the practice of any invention for which he holds a patent acquired under this Act on behalf of the United States. Any such license shall be granted under such terms and conditions as the agency head shall determine to be in the public interest. Any such license may be granted for the effective period of the patent or for a more limited period of time, and may be granted with or without the payment of royalty to the United States.

REPORTS TO THE CONGRESS

SEC. 9. The head of each agency which awards any contracts of the class described in section 3(a) shall submit semiannual reports to the Congress containing—

(a) the number of contracts executed for each of the subsections (a), (b), and (c) of section 4, and the number of inventions disclosed pursuant to such contracts;

(b) the number and general nature of such inventions with respect to which the agency acquired no greater rights than a royalty-free license in accordance with section 4, and a summary of the findings of fact upon which such determinations were made; and

(c) the number and general nature of such inventions with respect to which the agency has acquired greater rights than a royalty-free license in accordance with section 4 *and a summary of the findings of fact upon which a determination of the applicability of section 4 was based.*

SEVERABILITY CLAUSE

SEC. 10. If any provision of this Act, or the application of such provision to any person or circumstance, is held invalid, the remainder of this Act or the application of such provisions to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

TECHNICAL AMENDMENTS

SEC. 11. (a) Section 10(a) of the Act of June 29, 1935, as added by section 101 of the Act of August 14, 1946 (60 Stat. 1085, as amended; 7 U.S.C. 427i(a)) is amended by striking out the following language: "Any contracts made pursuant to this authority shall contain requirements making the results of research and investigations available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine."

(b) The National Science Foundation Act of 1950 is amended by striking out section 12 thereof (42 U.S.C. 1871).

(c) The Atomic Energy Act of 1954 is amended by striking out section 152 thereof (42 U.S.C. 2182).

(d) The National Aeronautics and Space Act of 1958 is amended by—

(1) striking out section 305 thereof (42 U.S.C. 2457); and

(2) by striking out in section 306 "the Inventions and Contributions Board, established under section 305 of this Act," and inserting in lieu thereof "an Inventions and Contributions Board which shall be established by the Administrator within the Administration."

(e) The Coal Research and Development Act of 1960 (74 Stat. 336) is amended by striking out section 6.

(f) The Helium Act Amendments of 1960 (74 Stat. 918) is amended by striking out the following language in section 4: "*Provided, however,* That all research contracted for, sponsored, cosponsored, or authorized under authority of this Act shall be provided for in such a manner that all information, uses, products, processes, patents, and other developments resulting from such research developed by Government expenditure will (with such exceptions and limitation, if any, as the Secretary may find to be necessary in the interest of national defense) be available to the general public: *And provided further,* That nothing contained herein shall be construed as to deprive the owner of any background patent relating thereto to such rights as he may have thereunder."

(g) The Saline Water Conversion Act of 1961 (75 Stat. 628) is amended by striking out section 4(b).

(h) The Arms Control and Disarmament Act of 1961 (75 Stat. 631) is amended by striking out section 32.

(7) provide, ~~in~~ the event a patent application is filed on any invention made by the contractor, appropriate means whereby the applicant shall be required to include within the first paragraph of the specification of such application and any patent issuing thereon, a statement specifying that the invention described therein shall be subject to the provisions of this Act;

(8) provide, in the event the contractor does not make a prompt ~~and full~~ disclosure *to the extent reasonably possible* to that agency of any invention made ~~in the course of or~~ under the contract, appropriate means whereby any rights of the contractor in such invention shall be void and such rights shall become the exclusive property of the head of that agency, on behalf of the United States, upon a determination made by such agency head, after affording the opportunity of a hearing to the contractor, that the contractor knowingly *and in bad faith* withheld rendering a prompt and full disclosure to that agency of such invention; and

(9) provide that nothing contained in this Act shall be construed as requiring the granting to the United States of any right or interest duly acquired in or with respect to any patent issued for any invention not made ~~in the course of or~~ under the contract.

PROPERTY RIGHTS OF *THE CONTRACTOR AND* THE UNITED STATES

SEC. 4. (a) The agency head ~~shall~~ *may* acquire, at the time of entering into the contract, on behalf of the United States, the principal ~~or exclusive~~ rights in any invention made by the contractor if:

(1) the purpose of the contract is to create, *or* develop, ~~or improve~~ *new* products, processes, or methods which are intended for commercial use by the general public, or which will be required for such use by governmental regulations *provided that such products, processes, or methods are of critical significance and that no reasonably competitive item is readily available*; or

(2) the purpose of the contract is for exploration into fields which directly concern *and are of critical significance in connection with* the public ~~health,~~ *health* ~~welfare,~~ *welfare* or safety; or

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

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

In exceptional circumstances the contractor may *retain* ~~acquire~~ at the time of contracting or upon disclosure of the invention, *notwithstanding the existence of any of the conditions specified in section 4(a) (1) to (4), inclusive,* greater rights than the nonexclusive license specified in section 3(b)(3) if the agency head *determines* ~~certifies~~ that such action will best serve the public interest.

(b) ~~Where~~ *Notwithstanding the provisions of section (4)(a), where* the purpose of the contract is to build upon existing knowledge or technology to develop information, products, processes, or methods for use by the Government, and the work called for by the contract is in a field of *science or* technology in which the contractor has acquired technical compentence directly related to an area in which he has an established nongovernmental commercial position, the agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after the invention has been identified, that there are *exceptional* ~~special~~ circumstances which indicate that the public interest would suffer as a result of the contractor retaining the principal or exclusive rights in such invention.

(c) As to any other contract executed under this Act that is not within the purview of subsections (a) and (*b*) ~~(c)~~ of this section, the determination of rights in any invention made by the contractor shall be made by the agency head after the disclosure required by section 3(b)(1) has been received. Upon receipt thereof, the agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after examination of the facts of the particular case, that there are ~~special~~ *exceptional* circumstances which indicate that the public interest would suffer as a result of the contractor acquiring the principal or exclusive rights.

During the post-World War II period we were the first to develop very high altitude parachutes for meteorological rockets, and proved their feasibility. We have had extensive experience in designing critical helmets for military aviators, as well as shrapnel-resistant helmets as used by tank crewmen. Our work includes the sturdy cross-slot webbing now used for cargo nets, safety equipment such as a carrier for live detonators, advanced heat-reflective clothing material, and other survival equipment.

It is discouraging to have created and developed intellectual property and to then have it appropriated.

We have presented our cases to administrative authorities. It is very unfortunate that the rationale of justification is more important than the determination of right.

We were encouraged, for example, on a crash basis, to develop a survival kit container for the Department of the Navy.

This item fitted into the framework of company policy in that it was for military usage. It was in an area of our technical competence and experience, and we could reasonably hope to produce the item on our present facilities. The Department of Defense was apparently to be the sole customer.

The requirement was urgent and deliveries were stated to be needed within 45 days after the award of a contract. It was agreed that Gentex would act only as a subcontractor, and would not submit a direct proposal as a prime contractor. The Gentex part number or equal was in the specification submitted with the invitation.

The prime contractor proceeded to reverse engineer the item after the award of the contract. The Navy then did three things:

1. The prime contractor was permitted to submit several prototypes, each of which reverse engineered our design. This was in violation of the Armed Services Procurement Regulations covering articles of brand name or equal. The material used was approximately one-fourth as costly as that which we found necessary to use to achieve proper function. The Navy's own specification drawn at a later date confirmed our determination for the use of the same expensive material.

2. The 45-day delivery requirement was extended more than 6 months to accommodate the prime contractor's desire to attempt to reverse engineer.

3. The contract was amended approximately 3 months after its award, without a reduction in price, to include a patent indemnity clause which would protect the Navy against a Gentex patent, should one thereafter be issued. (The clause employed was unusual in that it dealt not with patent indemnity generally, but singled out the Gentex Corp. specifically.)

The rationalization by administrative authorities for this action was that:

(1) There was then no valid issued patent.

(2) Gentex had sold a single container to the Department of Defense, which was not in fact so; that the Department therefore had the right to reverse engineer or to permit it to be reverse engineered.

(3) The prime contractor believed that he could make the article at less cost than we had quoted, and he was therefore entitled to reverse engineer it, even though performance under the contract was greatly delayed.

(4) Absence of consideration to the Government, despite the extended delivery and the known substitution of inexpensive material, was not considered relevant.

(5) Both the Navy and Gentex had been too informal in detailing of rights to intellectual property which might arise, and without any apparent regard to the extreme urgency and short term for performance of the program.

The correspondence is voluminous. (See exhibit 1.)[1]

Gentex developed an improved sound attenuating earcup for helmets which would permit the earcup to be oriented to the axis of the ear of the wearer.

The article was first submitted in small experimental quantities as a proprietary item to the Radio Corp. of America. The Radio Corp. of America submitted a drawing to the Air Force clearly marked that it was propietary to Gentex Corp. (General Textile Mills, Inc.)

The Department of the Air Force appropriated the design, transferred it to their own drawings, and asserted that they had a right to it in view of a contract they had with Radio Corp. of America. We protested this action several times verbally at a high administrative level.

[1] Contained in committee files.

apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material, the court may order such additional evidence to be taken by the agency head and to be considered in such manner and upon such terms and conditions as the court may deem proper. The agency head may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file such modified or new findings, and recommendations, if any, which, if supported by substantial evidence, shall be conclusive with respect to action in the matter under consideration. The judgment and decree of the court shall be final, except that it shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28, United States Code.

(c) Any declaration of acquiring or determination issued under this Act shall become final—

(1) upon the expiration of the time allowed for the making of application for an administrative hearing under this Act, if no such application is made within that time by the recipient of notice given under section 5(a) or by his duly authorized representative; or

(2) upon the expiration of the time allowed for filing a petition for judicial review, if no such petition has been duly filed within such time; or

(3) upon the expiration of the time allowed for filing a petition for certiorari if the order of the agency head has been affirmed or the petition for judicial review has been dismissed by a United States court of appeals, and no petition for certiorari has been duly filed; or

(4) upon the denial of a petition for certiorari, if the order of the agency head has been affirmed or the petition for review has been dismissed by a United States court of appeals; or

(5) upon the expiration of ten days from the date of issuance of the mandate of the Supreme Court, if such Court directs that the order of the agency head be affirmed or that the petition for review be dismissed.

INTERIM EXAMINATION OF PATENT APPLICATION

SEC. 7. Whenever the agency head makes a declaration of acquiring in accordance with the provisions of this Act, if he concludes that such invention may contain patentable subject matter, he may file with the Commissioner of Patents a patent application covering said invention, unless one has been filed by the contractor, even though such declaration of acquiring has not become final as provided in section 6 of this Act. The Commissioner of Patents shall examine such application, but shall not issue any patent thereon until he has been notified by the agency head that such declaration has become final, *in which case the patent shall issue to the Government as assignee*, or that a final determination has been made that the United States is not entitled to any rights greater than the nonexclusive license specified in section 3(b)(2) *in which case the patent shall issue to the inventor or his assignee.* The Commissioner of Patents shall proceed as provided in title 35, United States Code, except that nothing contained therein shall preclude a party who has successfully contested a declaration of acquiring from exercising all rights with respect to the securing of a patent on such invention that said party would have enjoyed if there had been no declaration of acquiring by the agency head.

PATENTS OF THE UNITED STATES

SEC. 8. (a) Whenever an agency head has taken title to any invention by declaration of acquiring which has become final or by authority of any other provision of this Act, and he has reason to believe that such invention is patentable, he may make application to the Commissioner of Patents for the issuance of a patent therefor to such agency head on behalf of the United States. If the Commissioner determines that such invention is patentable, he shall issue to such agency head on behalf of the United States a patent therefor. ~~Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.~~

The letters also discuss suggested procedural and policy changes.

The National Security Industrial Association recently held a series of nationwide briefing conferences, one of which was in New York on March 16 and 17, 1965. Every speaker for the Department of Defense stressed interest in receiving suggestions for development programs, with the concurrent statement that if the submitted program was of interest it would be funded by the Government. No interest was expressed for the submission of privately funded developments.

It appears self-evident that ideas which were only in the embryonic form would be submitted to the Department. Ideas would not be submitted for Government funding which had already been reduced to practice at the expense of the developer, and where the rights to related intellectual property would be entangled.

Economy in development work is obtained by many inventors, each working in his own field, creating progress in a sound, effective, economical, and democratic way. The inventors should be encouraged to present their ideas and products to any or many interested groups with confidence that their right to their intellectual property would be respected.

There is no present court or parajudicial court to review disputes arising out of violation of rights to intellectual property. An administrative settlement is slow and largely ineffective. Our own experiences have been poor and long delayed. The Office of the Comptroller General has little authority if any. The Armed Services Board of Contract Appeals has no authority, for invariably there is no contract existing covering the matter in question. A suit in the Court of Claims is long, involved, expensive, disconcerting, and few can afford the time, the dislocation of their normal effort, and the expense, considering the risk which is involved.

I did suggest to Congressman Emanuel Celler the creation of a parajudicial board patterned after the Armed Services Board of Contract Appeals, to hear matters involving the violation of intellectual property and other matters with the Department of Defense.

The practice of appropriation denies much of the fruits of further independent research and product improvement to the Government. The independent inventor, having once had his property appropriated, is reluctant to make further submissions. Improvements to the basic invention by the inventor who, by basic experience in the project is best qualified to make improvements, are therefore denied the Government.

The reduction of a device or improvement to practice invariably suggests improvements to the inventor. Grounded as he is in the basic elements of the design, these improvements are likely to be much more significant than are those which suggest themselves to one merely interested in appropriating by reverse engineering.

Gentex has continued to make submissions of inventions and product improvements only on a very selective basis. These submissions are made only to agencies where there is an expectation that our rights to the device or improvement will be protected. This is the Gentex experience and practice, but there are undoubtedly many other companies who, faced with the same problem, have either handled it as we have or have followed the policy of complete withholding of information.

Drying up the sources of progress is not the way this country's interests are best served. The country has grown strong by encouraging and rewarding productive effort. The denial of encourgement and reward can only destroy the historic basis of this country's progress. This we believe should be a matter of great concern to responsible legislative and administrative authorities.

Very respectfully submitted.

LEONARD P. FRIEDER, *President.*

GENERAL ELECTRIC CO.,
New York, N.Y., June 18, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, Washington, D.C.

DEAR SENATOR MCCLELLAN: I am writing you to express my personal views, and those of the General Electric Co., concerning pending legislative proposals respecting Government patent policy. I respectfully request that this letter be included in the record of the current hearings on these matters.

No company has a longer history of successful collaboration with its Government in respect to research and development for the national defense than does

(i) The Water Resources Research Act of 1964 (78 Stat. 329) is amended by striking out section 303.

(j) The Appalachian Regional Development Act of 1965 (79 Stat. 20) is amended by striking out section 302(d).

EFFECTIVE DATE

SEC. 12. This Act shall take effect on the first day of the fourth month beginning after the date of enactment of this Act.

GENTEX CORP.,
Carbondale, Pa., July 23, 1965.

CHAIRMAN, SENATE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS,
Washington, D.C.

DEAR SIR: In reporting prior proceedings of the Patents Subcommittee of the Senate Judiciary Committee remarks were attributed to you which indicated a greater concern on your part for the ethical implications in patent infringement than for possible material losses.

I am in complete accord with your viewpoint, and in a long history of contention with various Government groups, this has been our precise position.

The appropriation of data either before or after a patent is issued, when submitted in confidence or when confidence is clearly implied, constitutes, in my belief, an appropriation of intellectual property.

The fact that a material loss may be involved is incidental to the larger issue which you have cited. The practice is not isolated, is not unimportant. We believe that it is a violation of proper business practice.

As president of Gentex Corp., I desire in this context to present to you a brief résumé of some of this corporation's experience with the Department of Defense, particularly in relation to the appropriation of intellectual property.

We make this presentation as responsible citizens and in the belief that the best interests of the country will be served by frank discussion. We believe that there should be sincere evaluation of the impact the appropriation of intellectual property has on technological progress and on the patent system.

During the past quarter of a century the Gentex Corp. has been principally involved in developing products of military interest. All of our developments have been privately funded. No Government moneys have been used.

The Gentex Corp. has over 200 issued and pending patents. Most of these developments have been put to military usage. We have devised and developed the designs, presented the concept or product, and secured very few contracts for our efforts in these developments. This has been particularly so since World War II.

While we present the experience of a single company, it is reasonable that the same experiences could be recited by other companies. Still others may have had their intellectual property appropriated and then, being discouraged, discontinued submitting ideas.

There is no substitute for private and encouraged effort to achieve a high rate of technological progress. Technological progress is most economically obtained by the encouragement of private initiative. This is the foundation of our democratic system and upon which system this country grew strong and great.

The Gentex Corp.'s background is that of a company which has over the years been oriented to meeting military requirements. Corporate policy is that of using its own funds to finance the risks of development with the logical expectation that subsequent production would permit recovery, with profit, for the risked capital.

During World War II, we had the privilege of developing and producing, or only developing, solely with our own funds, the complete parachute assembly on the following assignments: The dropping of mines; the resupply of pigeons; the sonobuoy for locating submarines; drop sonde for securing weather data over inaccessible areas; essential cargo work for the Office of Strategic Services; the atomic bomb as dropped over Nagasaki and Hiroshima.

These were among our assignments. According to the best information available, there was not one single reported failure in a military operation. In accord with our own records, approximately 98 percent of our required raw materials were in the noncritical class.

dynamic Government patent policy, and for this principal reason favor S. 789 and S. 1809 over S. 1899.

I note that S. 1809 (as well as the other bills presently under consideration) provide that any exclusive rights retained by any contractor in any invention made in the performance of Government research and development are conditional on affirmative action taken by the contractor to develop the invention for commercial uses. Thus, the public interest is protected, and unless a contractor actually does respond to the patent incentives and applies private risk capital to these ends, the invention can be opened up to others who may.

I recognize that an acceptable patent policy must protect the public interest by seeing that private rights are not retained where such rights would frustrate either governmental contracting objectives or important considerations of public intereset. S. 789 and S. 1809 seek to accomplish this by specifying contracting situations in which the Government shall normally acquire principal or exclusive rights in inventions made in such situations. In the interest of flexibility S. 1809 then provides that the contractor may acquire greater rights than a nonexclusive license in such situations if the agency head certifies that such action is in the public interest. I believe that this is a sound approach and endorse it. I suggest, however, that some clarification of the guidelines may be useful to the administrator and the contractor alike.

First, I note the special interest and importance of the so-called cost sharing situation—the situation in which a Government contract requires work to be done which is only partially funded by the Government. I take it that there is general agreement that there are frequently contractor equities in such cases that would indicate contractor retention of more than simply a nonexclusive license and suggest that some specific recognition of this principle be included in the wording of S. 1809.

A special class of invention that I believe deserves differential treatment is that which the Kennedy policy calls nonprimary object inventions. The basic approach of defining contracting situations in which the Government will normally acquire principal rights to all contract-originated inventions assumes that most or all such inventions will be directly associated with the contract objective—the desired end product—and essential to the objective. This is far from the case. Although, hopefully, there are inventions of this type in each major development program, there are frequently secondary inventions—a temperature measuring device or a metal strengthening process, for example—that were used only incidentally in arriving at the desired end result and are by no means essential to duplicating that result in the future. It is these off-the-mainstream inventions that often show the greatest potential for commercial application. However, they most often need incentives to attract risk capital to bring this about. I, therefore, urge that provision be made for allotting the contractor primary rights in respect to this class of invention, regardless of what is done with "primary-purpose" inventions.

Related to the suggestion just made, there is perhaps not enough definition in S. 1809 of the "principal or exclusive rights" which the Government would acquire in certain cases. Do these terms necessarily equate to complete domestic and foreign title in the Government subject only to a nonexclusive license to the contractor? It seems undesirable to think in terms so completely black and white. Specifically in regard to the many inventions that will be made having multiple uses, the Government could appropriately acquire principal rights in its primary field of interest—agriculture or civil defense, for example—while at the same time permitting the contractor to retain limited exclusionary rights in other fields, thus affording an incentive to bring about further development, testing, etc., to put this technology to work in new fields.

Although I understand that it has been referred to in your current hearings, I believe that the importance of the interrelationship between Government patent policy and foreign trade can hardly be overemphasized. Since World War II, new and developing industries are emerging around the globe, and with improved transportation and communications, these industries are competing in a worldwide marketplace. The effects of this global competition are beginning to be felt dramatically in terms of the balance-of-payments problems confronting this Nation. President Johnson's export expansion program is a significant recognition of the importance of the ability of American industry to successfully compete in the worldwide marketplace in relation to our national welfare. The protection that the patent systems of all major industrial countries afford to cre-

We also included the earcup in two complete helmets submitted in confidence solely for evaluation to the Department of the Air Force. The special features of which helmets were clearly outlined in writing.

The Air Force subsequently asserted they had procured the design from Protection, Inc. This was, however, 2 years later than our experimental submission to Radio Corp. of America. The Air Force subsequently also asserted that they had secured the design from the Roanwell Corp. The matter is now before the Comptroller General. A copy of the protest to the Comptroller General is attached. (Exhibit 2)[1]

In the fields of protective helmets, parachutes, cargo nets, heat reflective material, carriers of live detonators, the story seems to be the same—creation, submission, acceptance, appropriation.

During the past year, the Department of Defense has issued a series of Defense procurement circulars which attempt to clarify the rights of inventors to intellectual property. There appears to be much confusion and lack of appreciation of these policies at the working level, perhaps in part because of the failure of these circulars to reach the root of the problem.

We have been told that we should not disclose an idea to anyone in the Department of Defense without a contract covering that disclosure. That the disclosure should not even be made to the contracting officer until after such a contract has been signed. This is obviously a condition which is impossible to fulfill.

In the light of this interdiction, however, the Office of General Counsel, Department of Defense, negotiated an agreement with us on behalf of the Department of the Navy, Bureau of Supplies and Accounts. The Bureau would not execute the agreement to effect a contract, despite pressure stated to have been exerted by the Office of General Counsel.

The agreement was to cover the test and evaluation of a superior heat reflective fabric which we had developed. The failure of the Bureau of Supplies and Accounts to enter into the agreement in accordance with the stipulations established by the Department of Defense precluded consideration of the item. The failure did underscore the impracticality of attempting to comply with the procedure regarded as essential to the protection of intellectual property.

We subsequently submitted the same heat reflective fabric to the Department of the Air Force, which they then permitted to be reverse engineered. The garment manufacturer who was the prime contractor under the Defense Clothing and Textile Supply Center, used our pricing, for ours was the only product available to the stated specification at the time of the original and even subsequent openings of the proposal under the invitation.

This reverse engineering, as with the survival kit, produced a product which was inferior. In order to make deliveries under the contract acceptable, the essential performance requirements for resistance to abrasion were lowered by 60 percent on the reverse engineered product. This reduction in quality level was without any apparent material consideration to the Government.

The preceding presentation details our experience in three specific instances.

Department of Defense policy with respect to patents and rights in data is, however, reflected in letters dated October 10, 1963, and October 23, 1963, attached hereto as exhibit 3.[1] These letters, between Gentex and the Honorable R. Tenney Johnson, then Deputy General Counsel of the Army, crystallize the issues involved. The corespondence is a discussion of a Department of Defense policy statement on matters of patent and intellectual property.

Briefly, there are three basic issues:

(1) That any appropriation of property rights by the Department of Defense is a violation of ethics and of rights guaranteed under the Constitution;

(2) That the purchase of a product resulting from a privately funded development by the Department of Defense does not of itself confer the right to the intellectual property which made such production possible;

(3) That quotations from nonpatent holders were frequently lower than those received from patent holders, even when the Department of Defense made allowance for reasonable royalties. It is pointed out that the royalty allowance is arbitrary, as selected by the Department of Defense without an analytical determination of its adequacy. Consideration is not given to the factors of risk, expense of development, or other pertinent elements of cost.

[1] Contained in committee files.

tial role in the success of the company's patent program. There was no lack of effort to promote them, but for various practical and commercial reasons, the effort did not succeed. Moreover, licenses under them have always been available to anyone who thought he could succeed.

Under the circumstances, we strongly urge the passage of your S. 1809. We would prefer to see it strengthened in certain areas to make more certain our unencumbered right to inventions, which are really the result of our own experience, know-how, and capital. We would be pleased to offer specific suggestions for amendment, should you so desire.

As to S. 1899, we think it fundamentally erroneous in philosophy and a serious danger to healthy development of inventions in the public and private interest.

Respectfully,

L. B. DODDS, *Vice President.*

INDUSTRIAL NUCLEONICS CORP.,
Columbus, Ohio, July 16, 1965.

Subject: Senate bill 1809.

Senator MCCLELLAN,
Chairman, Senate Judiciary Committee, Subcommittee on Patents, Trademarks, and Copyrights, Washington, D.C.

DEAR SENATOR MCCLELLAN: I regret that my schedule did not permit me to testify before your committee. I have, however, prepared a statement, in the appropriate number of copies, which I would like included as part of the record of the hearing on Senate bill 1809.

I would appreciate receiving a copy of the hearing testimony.

Sincerely,

HENRY R. CHOPE,
Executive Vice President.

STATEMENT OF HENRY R. CHOPE, EXECUTIVE VICE PRESIDENT, INDUSTRIAL NUCLEONICS CORP., COLUMBUS, OHIO

On behalf of Industrial Nucleonics Corp. of Columbus, Ohio, I am pleased to have this opportunity to present this statement for consideration by the Senate Subcommittee on Patents, Trademarks, and Copyrights. This statement is submitted in connection with Senate bill 1809 (McClellan), proposing a uniform national policy with respect to inventions resulting from Government-funded research and development.

We believe that the establishment of a uniform Government patent policy is important and will have far-reaching effects on the American economy. We believe that a properly worded statement of legislative intent and policy is needed to implement and expand the President's memorandum on Government patent policy dated October 10, 1963, and that most of the provisions of S. 1809 are appropriately directed to protection of the public interest without stifling free enterprise. I am therefore making this statement on behalf of Industrial Nucleonics Corp. in general support of the McClellan bill.

Our company is perhaps unique in making use of a new family of materials developed entirely at Government expense—namely, artificial radioisotopes developed and sold by the Atomic Energy Commission for use in commercial electronic measurement and control systems developed almost entirely at private expense by American industry. We hope that a brief history of the development and products of our company, and a brief statement of some of our recent specific problems in seeking to help Government agencies take advantage of our experience and know-how without compromising our background rights in inventions and technical data, may provide a case history helpful to this subcommittee.

INDUSTRIAL NUCLEONICS CORP.

Our company was formed only 15 years ago in Columbus, Ohio, by three young engineering-science graduates—of which I was one—with very little capital or prior business experience. By dint of hard work, good fortune, and some private financial backing, our company has very recently grown out of the "small business" category. We presently have approximately 600 employees of whom over one-fourth hold engineering or scientific college degrees.

General Electric Co. From its vital work in submarine detection in World War I to its equally vital roles in the development of radar, jet engines, and atomic energy in and after World War II, its cooperation with Government in the national interest has been continuous. Where national security has been at stake, contracting procedure has been given second place to meeting the national need. For example, during World War II, countermeasure equipment to jam radar detected on Japanese torpedo bombers was delivered within 9 days of the Government's request—obviously without regard to fine points of contractual paperwork.

In reviewing results at one of the company's plants during the war period, Secretary of the Navy, Frank Knox, made the statement: "No single industry in America has made a better response, a quicker response, to our appeal for help than General Electric. I don't think what you've done here can be duplicated anywhere in the world."

However, in a time when future governmental contracting policy is being studied—as it should be—through open congressional hearings, we believe it both proper and desirable that we state such views as our experience in Government research and development work has given us respecting patterns of contracting which we consider to be in the public interest.

As general manager of the Atomic Products Division of the General Electric Co. during the early postwar period, and as vice president-engineering of the company since 1960, I have had a deep interest in, and concern with, both the background matters referred to above and the issues discussed below.

I am familiar with the approaches represented by the several bills pending before the Senate's Patent, Trademark, and Copyright Subcommittee in its current hearings and believe that the preferred approach to solution is to be found in S. 1809. I construe this bill as one which places maximum reliance on private development of inventions while recognizing areas of special national interest which may require a measure of public control.

Patents are pieces of property, just like land and buildings, on which venture businesses are built. Patents in the public domain are just like any other public property—people don't build businesses on them. It is very true that some public land and some public buildings are needed—society, as a whole, uses them. But patents are different—they are either used for business purposes or not at all—by anyone.

Government itself has no need for the exclusionary powers afforded by patents. Government does not need power to exclude others from using inventions, nor would its doing so in any way advance the governmental objectives in funding research and development, the work of Government, or the public interest.

Research for itself does no good. The results of research do good when they show the way to goods or services that soviety values. Much research can only resut in showing that certain materials or equipment, if made available, would be useful. Privately owned patents can be incentive to business to make them available.

Although some minor part of results of Government-funded research and development may be readily usable in commercial products and services, it is usually the case that much more money and effort is required to develop an invention for commercial use than is spent in the original research. Extensive product and market development, including engineering development, testing, evaluation, and marketing effort, are essential to move these items into the commercial marketplace, and it is essential that private risk capital be attracted to accomplish these difficult and speculative tasks. Public funds and resources should rarely be used to undertake this kind of commercial risk venture.

As President Kennedy said in his statement of Government patent policy: "The public interest in a dynamic and efficient economy requires that effort be made to encourage the expeditious development and civilian use of these inventions. Both the need for incentives to draw forth private initiative to this end and the need to promote healthy competition in industry must be weighed in the disposition of patent rights under Government contracts."

In my understanding, the underlying philosophy and approach of S. 1809 (and of S. 789), as in the case of the Kennedy policy, is to permit private contractors to retain limited commercial rights wherever such rights are likely to provide needed incentive to call forth risk capital for the further development and utilization of technology. I believe this to be the keystone of an effective and

guage of the contract. A complete copy of the patent provisions for each of the listed contracts is found in appendixes I to V.

A. Navy Department

On June 28, 1964, Industrial Nucleonics Corp. entered into a contract with the Department of Navy, Bureau of Naval Operations (contract No. NOw 64–0551–f) for the study of various nuclear techniques to measure the corrosion of a metal coated with paint. This study involved the use of considerable background technology developed by Industrial Nucleonics Corp., including equipment and know-how. The contract patent provisions (see appendix I) provided that Industrial Nucleonics could obtain an exclusive license to any inventions conceived or made under the contract, with a nonexclusive, free license to the Government. Such a study contract conceivably opens the door to the private files of our company and is very dangerous to accept without some positive incentives. The contract provided the necessary incentive by holding out the opportunity to utilize the information and inventions developed for commercial equipment. Industrial Nucleonics accepted certain undesirable aspects of the contract, because of the protection which would be afforded on inventions which could have commercial use.

B. Department of Air Force

On June 25, 1963, Industrial Nucleonics Corp. entered into a contract with the Department of Air Force, Rome Air Development Center (contract No. AF 30 (602)—3123) for the evaluation of a system for tracking a missile during launch. The system had been conceived by Industrial Nucleonics Corp. prior to the contract and involved the use of nuclear techniques. Patent applications were filed before the contract on several inventions relating to missile lift-off measurement. The contract patent provisions (see appendix II) made no reference to background rights; i.e., a license to the Government in these inventions irrespective of whether they were first actually reduced to practice under the contract. Inventions developed under the contract were reported and the patent provisions provided that an exclusive license would be granted to us, with a license to the Government. The incentive for offering our inventions to the Government for possible first actual reduction to practice under a further contract was that inventions resulting from the initial contract and other contracts would be available, protected by an exclusive license, for commercial development. Again, Industrial Nucleonics Corp. utilized a great deal of its technical know-how and equipment to perform the initial contract. The Government had to come to Industrial Nucleonics Corp. not only for the technical know-how but for the inventions that could have solved their problem.

C. National Aeronautics and Space Administration

On June 24, 1964, Industrial Nucleonics Corp. entered into a contract with the National Aeronautics and Space Administration (contract No. NAS 8—11736) to evaluate the effectiveness of cryogenic propellant tank vent systems operating under or near zero-gravity conditions. This contract called for a wide range study of techniques for solving the problem, with specific emphasis on the applicability of nuclear measuring devices. Our special technology and know-how in this field was the reason for our receiving the contract. As a result of the contract, several inventions were conceived and reported to the Government. We are pleased to have been able to continue the work under a new contract through Douglas Aircraft, sponsored by NASA.

The inventions conceived under this contract may have commercial applications. Industrial Nucleonics realized the potential value of the developments. The patent provisions (see appendix III) provided for a petition of waiver of rights, which has been filed by Industrial Nucleonics Corp. for each of the inventions. Without this opportunity to obtain commercial rights, it is seriously doubted whether our corporation would have assumed such a small contract (about $18,000) to reveal all of the techniques and knowledge that we could muster to solve the Government's problem. It was the incentive for development of a commercial system that caused us to feel the advantages of outweighted the disadvantages, primarily due to the favorable patent provisions. It is our understanding that NASA is reasonable in its granting of such a waiver and our hope is that our corporation qualifies for it. We believe our company should qualify, if any corporation in the United States can qualify.

D. Atomic Energy Commission

On or about June 1965, Industrial Nucleonics Corp. obtained a development contract with the Atomic Energy Commission (contract No. AT (11–1)—1471) for study of the use of nuclear techniques and systems for maintaining helicopters in a desired formation. We had submitted a proposal to the AEC which suggested several possible systems. Apparently the AEC was quite impressed with our proposal and, obviously, the need for such a system is very great, in view of presently inadequate systems for maintaining helicopters in formation in bad weather.

The contract was preceded by long and strenuous negotiations with the AEC concerning patent rights. At times our judgment suggested that we should not accept a research and development contract from the AEC, in view of unfavorable patent provisions. Initially, the AEC people gave us little hope that concessions could be made as far as patent rights were concerned, in view of AEC's policies of obtaining background license rights as well as all title and rights to inventions related to atomic energy. Since this experience was our first encounter with the AEC, we were a little uncertain as to how the patent provisions would affect our company.

The patent provisions (see app. IV) which were eventually obtained clearly show how the AEC is unable, under present patent policies, to promote the development of nuclear technology and systems for commercial applications. Under the contract, Industrial Nucleonics first had to grant to the Government a background license in all inventions which were made before the contract and in any way involved in the contract work. Obviously, this provision raised a serious danger for us in guiding our engineers as to what to embody in the contract work. The AEC certainly could not expect us to use all the background technology we have. Consequently, the Government had the risk of receiving less than it might have obtained under a more favorable contract arrangement.

Another aspect of the contract, not so apparent to us at first, was the fact that Industrial Nucleonics would not be able to obtain an exclusive license for commercial use in any inventions useful in the field of atomic energy. This means that our company, basically devoted to the development of atomic energy applications, cannot under present policies and statutes realize exclusive patent rights to inventions arising out of work performed under AEC contracts for use in the field of atomic energy. Certainly, this leaves small incentive for any company with sizable private technology to deal with the AEC. More serious, from the viewpoint of the public interest, is the fact that the AEC is unable to realize greatest benefits from industry's potential contributions.

In this particular AEC contract, the "type C" patent provision was very carefully worded so that we obtained an exclusive license only in inventions "inherently capable of a use other than in the production or utilization of nuclear material or atomic energy." Unraveling this language: we could obtain an exclusive license only as to inventions outside our primary field of commercial interest. Further, such license was limited to the use of the invention "for applications other than use in the production or utilization of special nuclear material or atomic energy."

It is quite apparent that whatever exclusive license rights are obtained under the present "type C" AEC patent provisions, they are of very little value to a company in our commercial position.

E. Federal Aviation Administration

While our company has not yet obtained a contract with the FAA, it has presented several bid proposals. It is our understanding that the FAA follows AEC practices very closely. This fact has caused us some reservations in following up possible FAA contract opportunities. In addition, the FAA informed us by letter of May 12, 1956 (see app. V), that it would not accept any proposal for evaluation if marked with a "proprietary data" stamp. This has caused us further restraint in submitting any ideas to the FAA, since it is our normal policy to maintain a confidential status for the subject matter, to prevent creating a statutory bar. Other Government agencies do not appear to have this restrictive disclosure practice.

Summary of present patent rights distribution, as a contractor in the atomic energy field views it

Department or agency	Background rights to Government	Inventions made or conceived under contract	
		In atomic energy field	Other fields
Navy (DOD)	None, unless specially negotiated.	May receive exclusive license.	May receive exclusive license.
AF (DOD)	Same as above	Same as above	Same as above.
AEC	Required	No rights	May receive exclusive license.
NASA	None, unless specially negotiated.	Can petition for waiver of rights.	Can petition for waiver of rights.

ANALYSIS OF SENATE BILL 1809

We have carefully studied Senate bill 1809. It seems to resolve many of the difficulties we have experienced in working with the Government and in providing full support, using our substantial private technology. One reason why this bill meets with our favor is that the patent practice of each of the Government agencies would be placed on the same basis, yet with some flexibility.

As pointed out above, the AEC is completely different in its present approach and this has seriously affected our ability to contract with the AEC. We respectfully submit that the present AEC patent policies have hampered the development of atomic energy for commercial applications. S. 1809 appears to follow substantially the present patent practices of NASA and to provide some flexibility in a contract negotiation, depending on the circumstances. Hence, we generally support S. 1809.

PUBLIC BENEFIT DERIVED FROM PATENT PRACTICE INSTITUTED BY SENATE BILL 1809

We submit that the public will benefit by the adoption of S. 1809, especially in the field of atomic energy. As pointed out above, it is presently not possible for a company with substantial private technology and private inventions to work effectively with the AEC without giving up some of its own rights, especially if the subject matter has commercial applications.

In the alternative, some companies may take contracts from the Government, yet not use their best efforts, since certain private technology would be withheld to prevent granting a license to the Government, or making a disclosure of proprietary data to the Government. Of course, the risk of public disclosure of data is always present when dealing with the Government; but the possibility of obtaining exclusive rights to commercial developments can, in some instances, outweigh the disadvantages of such disclosure. We believe that developments in the field of atomic energy would be much more likely to get into the hands of the public under a more favorable AEC patent policy. Senate bill 1809 permits equitable contract arrangements which would encourage companies, such as ours, to work with the Government and ultimately make available to the public the byproducts of such work.

I thank you for the opportunity to present this information to your committee and I certainly would be glad to supplement any points where further information is necessary.

BIOGRAPHICAL SKETCH OF HENRY R. CHOPE, COLUMBUS, OHIO

Henry R. Chope was born in Louisville, Ky. He studied mathematics and science at the University of Louisville and was graduated from the Ohio State University in electrical engineering. He holds advanced degrees in engineering sciences and applied physics from both California Institute of Technology and from Harvard University.

During World War II, Mr. Chope served in the Armed Forces, specializing in development and use of electronic and radar equipment for meteorological

purposes and upper-air radiation research. He participated in many field experiments and tests, including radiation measurements in connection with the atomic tests at Bikini Atoll.

Mr. Chope was a founder and is presently executive vice president of Industrial Nucleonics Corp., Columbus, Ohio, which company was the first to specialize in industrial applications of atomic energy for on-line process measurement and control. He holds some 25 issues or pending U.S. patents in the fields of electronic and nuclear measurement, automatic controls, computers, and data processing, as well as numerous corresponding foreign patents.

He is a senior member of the Institute of Electrical and Electronic Engineers, of the Instrument Society of America, and of the American Institute of Industrial Engineers. He has membership in the American Nuclear Society, the American Association for the Advancement of Science, Tau Beta Phi, Beta Kapa Nu, and the Ohio and National Societies of Professional Engineers. Mr. Chope also participates as a member of the Labor-Management Committee of the Atomic Energy Commission, the Ohio Atomic Energy Advisory Board, and various committees of industry associations concerned with science, technology, and patents.

APPENDIX I

A. As used in this clause, the following terms shall have the meanings set forth below:

(i) The term "subject invention" means any invention, improvement, or discovery (whether or not patentable) conceived or first actually reduced to practice either—

(*a*) in the performance of the experimental, developmental, or research work called for or required under this contract; or

(*b*) In the performance of any experimental, developmental, or research work relating to the subject matter of this contract which was done upon an understanding in writing that a contract would be awarded: *Provided*, That the term "subject invention" shall not include any invention which is specifically identified and listed in the schedule for the purpose of excluding it from the license granted by this clause.

(ii) The term "technical personnel" means any person employed by or working under contract with the contractor (other than a subcontractor whose responsibilities with respect to rights accruing to the Government in inventions arising under subcontracts are set forth in (g) and (h) below), who, by reason of the nature of his duties in connection with the performance of this contract, would reasonably be expected to make inventions.

(iii) The term "subcontract" and "subcontractor" mean any subcontract or subcontractor of the contractor, and any lower tier subcontract or subcontractor under this contract.

B(1). The contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, and royalty-free license to practice, and cause to be practiced by or for the U.S. Government, throughout the world, each subject invention in the manufacturers, use, and disposition according to law, of any article or material, and in the use of any method. Such license (i) shall be nontransferable, except that the Government shall have the right to grant sublicenses to any foreign government or international organization specifically for use in programs established by international agreements for research, development, or production of weapons or equipment for mutual defense, and (ii) shall include the practice of subject invention in the manufacture, use, and disposition of any article or material, in the use of any method, or in the performance of any service acquired by or for the Government or with funds derived through the military assistance program of the Government or otherwise through the Government.

And the contractor hereby assigns to the Government all the rights that the contractor would have to enforce the subcontractor's obligations for the benefit of the Government with respect to subject inventions. If there are no subcontracts containing patent rights clauses, a negative report is required. The contractor shall not be obligated to enforce the agreements of any subcontractor hereunder relating to the obligations of the subcontractor to the Government in regard to subject inventions.

(i) The contractor recognizes that the Government, or a foreign government with funds derived through the military assistance program or otherwise through the U.S. Government, may contract for property or services with respect to which the vendor may be liable to the contractor for royalties for the use of a subject invention on account of such a contract. The contractor further recognizes that it is the policy of the Government not to pay in connection with its contracts, or to allow to be paid in connection with contracts made with funds derived through the military assistance program or otherwise through the U.S. Government, charges for use of patents in which the Government holds a royalty-free license. In recognition of this policy, the contractor agrees to participate in and make appropriate arrangements for the exclusion of such charges from such contracts or for the refund of amounts received by the contractor with respect to any such charges not so excluded.

NOTE.—Patent provisions of contract No. NOw 64-0551-f (Navy).

APPENDIX II

A. As used in this clause, the following terms shall have the meanings set forth below:

(i) The term "subject invention" means any invention, improvement, or discovery (whether or not patentable) conceived or first actually reduced to practice either—

(*a*) in the performance of the experimental, developmental, or research work called for or required under this contract; or

(*b*) in the performance of any experimental, developmental, or research work relating to the subject matter of this contract which was done upon an understanding in writing that a contract would be awarded; provided that the term "subject invention" shall not include any invention which is specifically identified and listed in the schedule for the purpose of excluding it from the license granted by this clause.

(ii) The term "technical personnel" means any person employed by or working under contract with the contractor (other than a subcontractor whose responsibilities with respect to rights accruing to the Government in inventions arising under subcontracts are set forth in (*g*) and (*h*) below), who by reason of the nature of his duties in connection with the performance of this contract, would reasonably be expected to make inventions.

(iii) The terms "subcontract" and "subcontractor" mean any subcontract or subcontractor of the contractor, and any lower tier subcontract or subcontractor under this contract.

B (1). The contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, and royalty-free license to practice, and cause to be practiced by or for the U.S. Government, throughout the world, each subject invention in the manufacture, use, and disposition according to law, of any article or material, and in the use of any method. Such license (i) shall be nontransferable, except that the Government shall have the right to grant sublicenses to any foreign government or international organization specifically for use in programs established by international agreements for research, development, or production of weapons or equipment for mutual defense and (ii) shall include the practice of subject invention in the manufacture, use, and disposition of any article or material, in the use of any method, or in the performance of any service acquired by or for the Government or with funds derived through the military assistance program of the Government or otherwise through the Government.

(2) With respect to:

(i) Any subject invention made by other than technical personnel; and

(ii) Any subject invention conceived prior to, but first actually reduced to practice in the course of, any of the experimental, developmental, or research work specified in (a) (i) above;

the obligation of the contractor to grant a license as provided in (b) (1) above, to convey title as provided in (d) (ii) (B) or (d) (iv) below, and to convey foreign rights as provided in (e) below, shall be limited to the extent of the contractor's right to grant the same without incurring any obligation to pay

royalties or other compensation to others solely on account of said grant. Nothing contained in this patent rights clause shall be deemed to grant any license under any invention other than a subject invention.

C. The contractor shall furnish to the contracting officer the following information and reports concerning subject inventions which reasonably appear to be patentable:

(i) A written disclosure promptly after conception or first actual reduction to practice of each such invention together with a written statement specifying whether or not a U.S. patent application claiming the invention has been or will be filed by or on behalf of the contractor;

(ii) Interim reports at least every 12 months, commencing with the date of this contract, each listing all such inventions conceived or first actually reduced to practice more than 3 months prior to the date of the report, and not listed on a prior interim report, or certifying that there are no such unreported inventions; and

(iii) Prior to final settlement of this contract, a final report listing all such inventions including all those previously listed in interim reports.

D. In connection with each subject invention referred to in C(i) above, the contractor shall do the following:

(i) If the contractor specifies that a U.S. patent application claiming such invention will be filed, the contractor shall file or cause to be filed such application in due form and time; however, if the contractor, after having specified that such an application would be filed, decides not to file or cause to be filed said application, the contractor shall so notify the contracting officer at the earliest practicable date and in any event not later than 8 months after first publication, public use, or sale.

(ii) If the contractor specifies that a U.S. patent application claiming such invention has not been filed and will not be filed (or having specified that such an application will be filed thereafter notifies the contracting officer to the contrary), the contractor shall:

(*a*) Inform the contracting officer in writing at the earliest practicable date of any publication of such invention made by or known to the contractor or, where applicable, of any contemplated publication by the contractor, stating the date and identity of such publication or contemplated publication; and

(*b*) Convey to the Government the contractor's entire right, title, and interest in such invention by delivering to the contracting officer upon written request such duly executed instruments (prepared by the Government) of assignment and application, and such other papers as are deemed necessary to vest in the Government the contractor's right, title, and interest aforesaid, and the right to apply for and prosecute patent applications covering such invention throughout the world, subject, however, to the rights of the contractor in foreign applications as provided in (e) below, and subject further to the reservation of a nonexclusive and royalty-free license to the contractor (and to his existing and future associated and affiliated companies, if any, within the corporate structure of which the contractor is a part) which license shall be assignable to the successor of that part of the contractor's business to which such invention pertains;

(iii) The contractor shall furnish promptly to the contracting officer on request an irrevocable power of attorney to inspect and make copies of each U.S. patent application filed by or an behalf of the contractor covering any such invention;

(iv) In the event the contractor, or those other than the Government deriving rights from the contractor, elects not to continue prosecution of any such U.S. patent application filed by or on behalf of the contractor, the contractor shall so notify the contracting officer not less than 60 days before the expiration of the response period and, upon written request, deliver to the contracting officer such duly executed instruments (prepared by the Government) as are deemed necessary to vest in the Government the contractor's entire right, title, and interest in such invention and the application, subject to the reservation as specified in D(ii) above; and

(v) The contractor shall deliver to the contracting officer duly executed instruments fully confirmatory of any license rights herein agreed to be granted to the Government.

E. The contractor, or those other than the Government deriving rights from the contractor, shall, as between the parties hereto, have the exclusive right to file applications on subject inventions in each foreign country within:

(i) Nine months from the date a corresponding U.S. application is filed;

(ii) Six months from the date permission is granted to file foreign applications where such filing had been prohibited for security reasons; or

(iii) Such longer period as may be approved by the contracting officer.

The contractor shall, upon written request of the contracting officer convey to the Government the contractor's entire right, title, and interest in each subject invention in each foreign country in which an application has not been filed within the time above specified, subject to the reservation of a nonexclusive and royalty free license to the contractor together with the right of the contractor to grant sublicenses, which license and right shall be assignable to the successor of that part of the contractor's business to which the subject invention pertains.

F. If the contractor fails to deliver to the contracting officer the interim reports required by (c) (ii) above, or fails to furnish the written disclosures for all subject inventions required by (c) (i) above shown to be due in accordance with any interim report delivered under (c) (ii) or otherwise known to be unreported, there shall be withheld from payment until the contractor shall have corrected such failures either ten (10) percent of the amount of this contract, as from time to time amended, or $5,000, whichever is less. After payment of 80 percent of the amount of this contract, as from time to time amended, payment shall be withheld until a reserve of either 10 percent of such amount, or $5,000, whichever is less, shall have been set aside, such reserve or balance thereof to be retained until the contractor shall have furnished to the contracting officer:

(i) The final report required by (c) (iii) above;

(ii) Written disclosures for all subject inventions required by (c) (i) above which are shown to be due in accordance with interim reports delivered under (c) (ii) above, or in accordance with such final reports, or are otherwise known to be unreported; and

(iii) The information as to any subcontractor required by (h) below.

The maximum amount which may be withheld under this paragraph (f) shall not exceed 10 percent of the amount of this contract or $5,000, whichever is less, and no amount shall be withheld under this paragraph (f) when the amount specified by this paragraph (f) is being withheld under other provisions of this contract. The withholding of any amount or subsequent payment thereof to the contractor shall not be construed as a waiver of any rights accruing to the Government under this contract. This paragraph (f) shall not be construed as requiring the contractor to withhold any amounts from a subcontractor to enforce compliance with the patent provisions of a subcontract.

G. The contractor shall, unless otherwise authorized by the contracting officer as hereafter provided, include a patent rights clause containing all the provisions of this patent rights clause except provision (f) in any subcontract hereunder of $3,000 or more having experimental, developmental, or research work as one of its purposes. In the event of refusal by a subcontractor to accept such a patent rights clause, the contractor (i) shall promptly submit a written report to the contracting officer setting forth the subcontractor's reasons for such refusal and other pertinent information which may expedite disposition of the matter, and (ii) shall not proceed with the subcontract wihout the written auhorization of the contracting officer. Reports, instruments, and other information required to be furnished by a subcontractor to the contracting officer under the provisions of such a patent rights clause in a subcontract hereunder may, upon mutual consent of the contractor and the subcontractor (or by direction of the contracting officer) be furnished to the contractor for transmission to the contracting officer.

H. The contractor shall, at the earliest practicable date, notify the contracting officer in writing of any subcontract containing one or more patent rights clauses; furnish the contracting officer a copy of each of such clauses; and notify the contracting officer when such subcontract is completed. It is understood that with respect to any subcontract clause granting rights to the Government in subject inventions, the Government is a third party beneficiary; and the contractor hereby assigns to the Government all the rights that the contractor would have to enforce the subcontractor's obligations for the benefit of the Government with respect to subject inventions. If there are no subcontracts containing patent rights clauses, a negative report is required. The contractor shall not be obli-

gated to enforce the agreements of any subcontractor hereunder relating to the obligations of the subcontractor to the Government in regard to subject inventions. (i) The contractor recognizes that the Government, or a foreign government with funds derived through the military assistance program or otherwise through the U.S. Government, may contract for property or services with respect to which the vendor may be liable to the contractor for royalties for the use of a subject invention on account of such a contract. The contractor further recognizes that it is the policy of the Government not to pay in connection with its contracts, or to allow to be paid in connection with contracts made with funds derived through the military assistance program or otherwise through the U.S. Government, charges for use of patents in which the Government holds a royalty-free license. In recognition of this policy, the contractor agrees to participate in and make appropriate arrangements for the exclusion of such charges from such contracts or for the refund of amounts received by the contractor with respect to any such charges not so excluded.

NOTE.—Patent provisions of Contract No. AF 30(602)-3123 (Air Force).

APPENDIX III

A. As used in this clause and in the property rights in inventions clause of this contract, the following terms have the meanings assigned:

(i) "Reportable item" means any invention, discovery, improvement or innovation, whether or not the same is susceptible of protection under the U.S. patent laws, which is made in the performance of work under this contract or in the performance of any work done upon an understanding in writing that this contract would be awarded;

(ii) "Made" means conceived or first actually reduced to practice, and "making" means conceiving or first actually reducing to practice;

(iii) "Invention" means any reportable item which appears to fall within a statutory class of patentable subject matter (35 U.S.C. 101 and 171) and which has a reasonable possibility of being patentable;

(iv) "Subcontract" and "subcontractor" means any subcontract or subcontractor of the contractor, and includes any lower tier subcontract or subcontractor under this contract;

(v) When this clause and the property rights in inventions clause are included in any subcontract, "contractor" shall be read as "subcontractor" and "contract" shall be read as "subcontract";

(vi) "Person" means any individual, partnership, group, corporation, association, institution or other entity; and

(vii) "Administrator" includes the Administrator of NASA and his duly authorized representative.

B. The contractor shall conduct a continual review of the results of the work performed under this contract for the purpose of identifying reportable items and shall furnish promptly to the contracting officer a written report concerning each reportable item. Such report shall include:

(i) Such technical detail as is necesary to identify, describe, and convey an understanding of the nature, purpose, operation, and physical (electrical, chemical, etc.) characteristics of each reportable item;

(ii) A designation of each reportable item considered by the contractor to constitute an invention;

(iii) A statement which sets forth the relationship of each reportable item to the present contract work; and

(iv) A statement of all apparent uses in which each reportable item may find application.

C. In addition to the report required in (b) above, the contractor shall furnish to the contracting officer within 1 month following each semiannual anniversary date of this contract a summary of the review activities undertaken and the results thereof which shall include:

(i) A written report as required by (b) above for each reportable item not previously reported;

(ii) A statement listing each subcontract containing this reporting of new technology clause and the property rights in inventions clause, stating the name, and address of each subcontractor, describing the work to be performed, and giving the estimated completion date of each subcontract.

D. After completion of the contract work and prior to final payment, the contractor shall furnish a report:

(i) Listing all reportable items or certifying that there were no reportable items; and

(ii) Confirming or correcting previous information submitted regarding subcontracts, or certifying that no such subcontracts were awarded.

E. (1) In each subcontract hereunder involving research, experimental, design, engineering, or development work, the contractor shall include the property rights in inventions clause of this contract and this clause, except for paragraph (f) below.

(2) In each subcontract hereunder of over $50,000 which calls for work of the type described in (e)(1), the contractor shall, prior to tendering final payment:

(i) Obtain from an official having authority to execute such subcontract on behalf of the subcontractor, a letter certifying compliance by the subcontractor with this clause and the property rights in inventions clause of this contract; and

(ii) Submit a copy of such letter to the contracting officer.

(3) In the event of refusal by a subcontractor to accept this clause and the property rights in inventions clause or either of them, the contractor shall promptly notify the contracting officer of such refusal and shall not execute the subcontract in question until provisions have been approved in writing by the contracting officer for inclusion in said subcontract.

F. (1) Except as provided in subparagraph (2) below, if the contractor fails to comply with the provisions of this clause or of the property rights in inventions clause of this contract, there shall be withheld from payment, until such failures have been corrected, either 10 percent of the amount of this contract, or $50,000, whichever is less. After payment of 85 percent of the amount of this contract, as from time to time amended, payment shall be withheld until a reserve of either 10 percent of such amount, or $50,000, whichever is less, shall have been set aside, such reserve or balance to be retained until the contractor shall have complied with the provisions of this clause and the property rights in inventions clause as aforesaid. In the event that the contractor does not comply with the provisions aforesaid within 1 year after final payment (exclusive of the amount withheld) of this contract, any amount actually withheld under the provisions of this contract and authorized to be withheld under this paragraph (f) shall be deemed to be liquidated damages for noncompliance with this clause. No amount shall be withheld under this paragraph (f) so long as the amount specified in this paragraph (f) is being withheld under other provisions of this contract. The payment of any amount or withholding thereof under this paragraph (f) shall not be construed as a waiver of any rights accruing to the Government under this contract.

(2) Subparagraph (1) does not apply when the contract is a no fee contract with an educational institution. In no fee contracts with nonprofit institutions other than an educational institution, the percentage amount specified to be withheld in subparagraph (1) above is reduced from 10 percent to 1 percent.

G. The Government may duplicate, use, and disclose in any manner and for any purpose whatsoever, and have others so do, all reports required by paragraphs (b) and (c) of this clause.

23. PROPERTY RIGHTS IN INVENTIONS (NOVEMBER 1962)

A. (1) An invention reported under the reporting of new technology clause of this contract shall be presumed to have been made by a person described in paragraphs (1) or (2) of section 305(a) of the National Aeronautics and Space Act of 1958 (hereinafter called "the act"), and under the conditions therein described.

(2) With respect to these inventions designated as such by the contractor at the time of reporting, the presumption of (a)(1) above shall be conclusive unless the contractor at the time of reporting any such invention does one of the following:

(i) Submits to the contracting officer a written statement, containing supporting details, demonstrating that the invention had not been made under the circumstances set forth in either paragraph (1) or (2) of section 305(a) of the act; or

(ii) Notifies the contracting officer of the contractor's intention to file a petition for waiver of the rights of the United States to such invention, and files such petition within 3 months of such notification.

(3) With respect to other inventions, the presumption of (a)(1) above shall be conclusive if the contractor fails to take one of the actions set forth in (a)(2) above within 30 days after notification by the Administrator that the reportable item has been determined to constitute an invention.

B(1). If the contractor files a petition for waiver, he may nevertheless file the statement described in (a)(2) above. With or without a petition for waiver, the Administrator will review the information furnished by the contractor in such statement and any other available information relating to the circumstances surrounding the making of the invention and will notify the contractor of the decision as to whether the invention had been made under the circumstances set forth in either paragraphs (1) or (2) of section 305(a) of the act.

(2) If the contractor notifies the contracting officer of his intention to petition for waiver as provided in (a)(2) above, but either (i) fails to file his petition within the time specified therein, or (ii) at the time of filing a petition for waiver, does not file an accompanying written statement in accordance with (a)(2) above, the presumption stated in (a)(1) above shall become conclusive.

c. With respect to each invention which becomes the exclusive property of the United States, contractor shall:

(i) Notify the contracting officer promptly following any public use or sale by the contractor of the invention or any publication by the contractor describing such invention; and

(ii) Furnish, upon written request by the contracting officer, such full and complete technical and other information available to the contractor as will be adequate for ready transposition to patent specification form and for effective prosecution of a patent application, and, in addition, shall execute or secure execution of documents and instruments as may be determined by the Administrator to be necessary for the preparation and prosecution of applications for letters patent covering each invention.

NOTE.—Patent Provisions of Contract No. NAS 8-11736 (NASA).

APPENDIX IV

A. Whenever any invention or discovery is made or conceived by the contractor or its employees in the course of or under this contract, which invention or discovery is inherently incapable of a use other than in the production or utilization of special nuclear material or atomic energy, the contractor shall promptly furnish the Commission with complete information thereon; and the Commission shall have the sole power to determine whether or not and where a patent application shall be filed, and to determine the disposition of the title to and rights in and to any invention or discovery and any patent application or patent that may result: *Provided, however,* That if the contract, when furnishing the complete information as to any invention or discovery advises the Commission that the contractor will file at its own expense, subject to security requirements and regulations, a U.S. patent application within 6 months of reporting, and designated foreign patent applications on such invention or discovery, subject to security requirements and regulations, the contractor shall retain:

(1) A nonexclusive, irrevocable, paid-up license for all purposes in any such U.S. patent application filed by the contractor and any U.S. patent issued thereon, and

(2) The title and rights in any such foreign patent applications or foreign patents secured by the contractor, subject to:

(i) A nonexclusive, irrevocable, paid-up license to the U.S. Government for U.S. governmental purposes and with the right of the U.S. Government to grant licenses to foreign governments for purposes of governmental use by such foreign governments pursuant to a treaty or agreement with the U.S. Government or any agency thereof.

(ii) Granting, upon request, nonexclusive royalty-free licenses to U.S. citizens, and to U.S. corporations when 75 percent or more of the voting interest is owned by U.S. citizens, for use in the production or utilization of special nuclear material or atomic energy; and agreeing to grant to foreign users and purchasers of the product of such a U.S. licensee a license, to use or sell such product to an assignee of the business or plant or as surplus, at a reasonable, nondiscriminatory royalty ordinarily to be at no greater royalty than contractor has charged its other foreign licensees.

(iii) The right of the contractor to grant such other licenses in accordance with applicable statutes and regulations.

(*a*) *Provided*, That if the contractor grants any licenses other than as provided in (ii) above, the same shall be for reasonable royalties or compensation, and

(*b*) *Provided further*, That if, after 3 years of the issuance of a particular foreign patent, contractor, its assignee or its licensees cannot demonstrate, upon Commission request, the practical application of the subject matter covered by such foreign patent, the contractor or its assignee shall, at the Commission's request, grant licenses on any such foreign patent to others at reasonable royalties.

(3) If the contractor does not desire to prosecute the U.S. patent application or any foreign application or maintain any foreign patent, the contractor, prior to abandonment shall afford the Commission an opportunity to take over prosecution of any such patent application or maintain any patent. The judgment of the Commission on these matters shall be accepted as final; and the contractor, for itself and for its employees, agrees that the inventor or inventors will execute all documents and do all things necessary or proper to carry out the judgment of the Commission.

B. Whenever any invention or discovery is made or conceived by the contractor or its employees in the course of or under this contract, which invention or discovery is inherently capable of a use other than in the production or utilization of special nuclear material or atomic energy, the contractor shall promptly furnish the Commission with complete information thereon; and the Commission shall have the sole power to determine whether or not and where a patent application shall be filed, and to determine the disposition of the title to and rights in and to any invention or discovery and any patent application or patent that may result:

Provided, however, That if the Commission determines not to file, the contractor may file any U.S. and foreign patent application subject to the Commission security requirements and regulations.

Provided, however, That the contractor in any event shall retain at least a sole (except as against the Government or its account), irrevocable, royalty-free license with the sole right to grant sublicenses, under said invention, discovery, patent application or plant, such license and sublicensing rights being limited to the manufacture, use and sale for purposes other than use in the production or utilization of special nuclear material or atomic energy. Subject to the license retained by the contractor, as provided in this paragraph, the judgment of the Commission on these matters shall be accepted as final; and the contractor, for itself and for its employees, agrees that the inventor or inventors will execute all documents and do all things necessary or proper to carry out the judgment of the Commission.

C. No claim for pecuniary award or compensation under the provisions of the Atomic Energy Act of 1954, as amended, shall be asserted by the contractor or its employees with respect to any invention or discovery made or conceived in the course of or under this contract.

D. Except as otherwise authorized in writing by the Commission, the contractor will obtain patent agreements to effectuate the purposes of paragraphs A, B, and C of this article from all persons who perform any part of the work under this contract, except such clerical and manual labor personnel as will not have access to technical data.

E. Except as otherwise authorized in writing by the Commission, the contract will insert in all subcontracts the Commission's standard type A patent provision.

F. It is recognized that during the course of the work under this contract, the contractor or its employees may from time to time desire to publish, within the limits of security requirements, information regarding scientific or technical developments made or conceived in the course of or under this contract. In order that public disclosure of such information will not adversely affect the patent interests of the Commission or the contractor, patent approval for release and publication shall be secured from the Commission prior to any such release or publication.

G. With respect to each invention or discovery in which the contractor is granted the principal or any exclusive rights under paragraph (b) of this article, the contractor agrees to provide written reports at reasonable intervals when requested by AEC as to:

(1) The commercial use that is being made or is intended to be made of such invention or discovery; and

(2) The steps taken by the contractor to bring the invention to a point of practical application or to make the invention or discovery available for licensing.

H. With respect to each invention or discovery in which the contractor is granted the principal or any exclusive rights under paragraph B of this article, the contractor agrees to and does hereby grant the Commission:

(1) The right to require the granting of nonexclusive, royalty-free licenses to applicants on any such invention or discovery unless the contractor, its transferees, or assignees demonstrate to the Commission, on request, that the contractor, its transferees, or assignees have taken effective steps within 3 years after a patent issues on such invention or discovery to bring the invention or discovery to a point of practical application, or have granted licenses thereon free or on reasonable terms, or can show cause why he, his transferees, or assignees should retain the principal or exclusive rights for a further period of time; and

(2) The right to grant licenses royalty-free or on reasonable terms to the extent that the invention or discovery is required for public use by governmental regulation, or as may be necessary to fulfill health needs, or for other public purposes stipulated in this contract.

I. In addition to the rights of the parties under the foregoing paragraphs in and to inventions or discoveries made or conceived in the course of or under this contract, the contractor agrees to and does hereby grant to the Government an irrevocable, nonexclusive, paid-up license in and to any and all inventions or discoveries of the contractor made, developed, or acquired prior to or on the effective date of expiration or completion of this contract, which are incorporated in any conceptual design or prototype furnished under this contract: (a) to make, use, and to have made and used the invention or discovery throughout the world, for U.S. Government purposes, for use in helicopter formation keeping systems, and (b) to sell and have sold any article, material, or product embodying said invention or discovery, and acquired or used under the foregoing license, as surplus or condemned public property as provided by law. Provided, however, that no license is granted herein as respects any item which, on the effective date of this contract, is a standard commercial item of the contractor. The acceptance or exercise by the Government of the aforesaid rights and license shall not prevent the Government at any time from contesting the enforceability, validity or scope of, or the title to, any rights or patents herein licensed.

All drawings, sketches, designs, design data, specifications, notebooks, technical and scientific data, and all photographs, negatives, reports, findings, recommendations, data and memorandums of every description relating thereto, as well as all copies of the foregoing, developed, prepared or furnished under this contract, shall be subject to inspection by the Commission at all reasonable times (for which inspection the proper facilities shall be afforded the Commission by the contractor and its subcontractors), shall be the property of the Government and may be used by the Government for any purpose whatsoever without any claim on the part of the contractor and its subcontractors and vendors for additional compensation and shall, subject to the right of the contractor to retain a copy of said material for its own use, be delivered to the Government, or otherwise disposed of by the contractor either as the contracting officer may from time to time direct during the progress of the work or in any event as the contracting officer shall direct upon completion or termination of this contract. The contractor's right of retention and use shall be subject to the security and patent provisions, if any, of this contract.

NOTE.—Patent provisions for contract No. AT (11-1)-1471 (AEC).

APPENDIX V

FEDERAL AVIATION AGENCY,
Washington, D.C., May 12, 1965.

INDUSTRIAL NUCLEONICS CORP.,
Columbus, Ohio

(Attention: Mr. Charles Badget.)

DEAR MR. BADGET: I wish to thank you for your consideration in forwarding a copy of your "Proposals for Digital Barometric Pressure Sensing Device Using Nucleonic Techniques" to our Agency.

A policy within the Agency does not permit us to review any material which is proprietary in nature. We respect the rights of the firms with whom we deal

and treat the proposals in an ethical manner. However, we find it necessary to return any proposals with a proprietary statement to the submitter without comment and without a review on our part. If you desire to delete the proprietary statement and to resubmit the proposal, we shall consider it along with other information that we have received on the subject.

Sincerely yours,

EDMUND BROMLEY, JR.,
Chief, Support Systems Branch,
Environmental Development Division,
Systems Research and Development Service.

INTERNATIONAL BUSINESS MACHINES CORP.,
Armonk, N.Y., June 2, 1965.

Hon. Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

MY DEAR SENATOR: I wish to offer my endorsement and support of the general principles contained in your bill S. 1809.

As you may recall, I endorsed the middle ground approach of your previous bill S. 1290 in my letter of May 7, 1963. In my opinion, your present bill represents a substantial improvement over S. 1290 in assuring the contractor of a royalty-free license and providing for a determination of invention rights at the time of contracting.

I suggest the following additional improvements for your consideration.

1. Where a contractor has filed a patent application or obtained a patent on an invention prior to entering into a contract, the Government's right should be limited to the normal nonexclusive license, even though the invention is first actually reduced to practice under the contract.

2. The Government should dedicate the inventions it acquires to the public rather than entering the business of licensing its patents on a royalty basis.

I hope these comments will be of assistance to you in resolving this complex problem and wish you utmost success in this bill.

Very truly yours,

J. W. BIRKENSTOCK, *Vice President.*

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
July 9, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Judiciary Committee, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Mr. Howard Forman, an industry witness, appeared before your subcommittee on July 7. In his testimony he quoted from a statement given in 1959 by a witness representing the American Patent Law Association before a subcommittee of the House Committee on Science and Astronautics, in which he submitted the names of five companies which purportedly had declined to accept contracts with NASA because of its patent policy.

In this connection, it may be useful to cite certain testimony in 1962 before the Monopoly Subcommittee of the Senate Small Business Committee by the General Counsel of the National Aeronautics and Space Administration. The following colloquy took place:

"Senator LONG. Do you know of any large concern which has refused to contract with you unless they get patent rights?

"Mr. JOHNSON. We submitted a list to another congressional committee of certain instances * * * *There have been a few such instances. In almost every case, by the time we were able to sit down and talk it out with them the contract was accepted.*"[1] (Emphasis added.)

In further hearings conducted by the same subcommittee in 1963 on the same subject, the following colloquy took place between the NASA Administrator and the subcommittee chairman:

[1] Hearings before the Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate, Mar. 27, 1962.

"Senator LONG. * * * Now, do you presently feel that you are not able to get a sufficient number of contractors available for research on your research and development contracts?

"Mr. WEBB. Generally, we have a large number of people who want to do work. The number of people qualified to do the highest quality of work is not large, but I think the patent waiver features of our law are not restricting us with respect to good contractors, although they are more restricted than other Government departments, as you know."[2]

I respectfully request that this letter be inserted at an appropriate place in the record so that a reader of Mr. Forman's testimony will be aware of this additional information.

Sincerely,

RUSSELL B. LONG,
Chairman, Monopoly Subcommittee.

BROWNE, SCHUYLER & BEVERIDGE,
ATTORNEYS AND COUNSELORS AT LAW,
Washington, D.C., August 31, 1965.

MR. THOMAS C. BRENNAN,
Chief Counsel, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. BRENNAN: Concerning the testimony obtained during hearings on S. 1809, it may be of interest to point up a factor often overlooked in debates on what should be the legislative policy for apportionment of rights as between the Government and the inventor and/or developer of inventions important to the public welfare. This factor comes into play when legislation or executive policy seeks to assure by a general rule the public ownership for, and cancellation of, private rights where the Government has made a substantial or predominant contribution to the total development cost. In assuring such public ownership in cases where there are equities to favor that result it may often happen, in practice, that the private inventor or contributor has an equity which is wholly cut off unless care is taken to preserve his private right; and to respect the final clause of amendment V to the Constitution.

The U.S. Government experiences a very strong bargaining position in letting contracts to contractors dependent on such contracts for sizable portions of their business, and this position is not usually challenged. An important inequality arises where general regulations and administrative policies control individual cases rather than the equities of the case themselves. Nor is the private party always in a position of equality to test in court the application of administrative policy, since courts have a tendency to require proof that an administrator has exercised his authority in an arbitrary or capricious manner under a regulation before relief will be granted. Against these principles governing right to relief, supported by the sometimes overwhelming weight of legal talent available to the Government, the individual or small company finds it not worthwhile to challenge an administrative decision, if based plausibly on a general provision of law or a departmental regulation.

An example arises from closer review of the case reported by Mr. Walter A. Munns, President, Smith Kline & French Laboratories, in his statement to the committee on August 19, 1965. That case relates to cooperative work between a company and a research worker who was paid in part under a grant from the Department of Health, Education, and Welfare for investigations of steroids, for which $26,000 was expended each year for several years, but not directed at all to the subject of the cooperative work. Who first suggested that results of his study could be of possible use as a prescription drug to prevent incipient heart attack seems not to be clear. The suggestion that a particular steroid was worth further investigation for that purpose seems to have come wholly from the company. It appears further that no such use had been suggested or recognized as a result of his contract reports to the Government Department, and that if any suggestion was made, it was not seen to have value.

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[2] "Economic Aspects of Government Patent Policies," hearings before a subcommittee of the Select Committee on Small Business, U.S. Senate, Mar. 14, 1963, p. 317.

From this point the private company expended $250,000 to evaluate the drug for this new and urgent purpose, and proceeded to the point of proving its effect and safety in animal tests.

Now we have a contribution of a small sum, certainly not higher than the $26,000 allocated for general steroid research in one year, which could be regarded as the Government's contribution, and a private contribution some 10 times larger. Yet the company, despite its overwhelmingly larger contribution of $2 million required for producing an acceptable pharmaceutical product was denied any private right even though its contribution might then exceed 98 percent of the total cost of development.

It has long been urged by many that the doctrine of encouraging innovations and inventions should give way to the doctrine that he who pays for a development should own it. Yet the same doctrine of equitable ownership, when put into effect as between Government and its citizens as innovators, seeks to assert full ownership were private costs may be as much as 50 times greater than that of the Government. This is an example, perhaps extreme, but nevertheless real, of equities quite opposite to those often assumed to prevail generally.

Should not any general legislation carefully guard against the image of a Government which takes away from its citizens what they may contribute at private expense as well as protecting other public interests?

This letter is submitted on my own behalf for record purposes in the hope that ultimate legislation will not unfairly tip the balance in favor of big Government to the ultimate detriment of the people governed.

Sincerely,

WILSON R. MALTBY.

MINNESOTA MINING & MANUFACTURING CO.,
St. Paul, Minn., July 19, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: In the interest of clarifying proposed patent legislation before the Senate, the Minnesota Mining & Manufacturing Co. wishes to make a statement for the record, expressing itself with some amendments for Senate bill 1809. These amendments are prepared in an effort to provide more equitable treatment for contractors who carry out research and development contracts on behalf of the Government.

We wish to commend the Subcommittee on Patents, Trademarks, and Copyrights for the long extended hearings in the interest of developing sound governmental contract procedure. Of the bills presented at the hearing, Senate 1809, in our opinion, offers the best proposal for the establishment of uniform governmental contracts in the field of research and development. The committee has heard many times the various arguments regarding patent policies so we will devote our further efforts to the proposed amendments.

In the definitions, section 2, paragraph (c) should be revised to read:

"(c) The term 'contract' means any contractual arrangement set forth in writing, entered into between any Government agency and any other person where a purpose of the contract is the conduct of experimental, developmental, or research work, and the contract involves the expenditure of Government funds to reimburse the contractor for the conduct of the work. Such term includes any assignment, substitution of parties, or subcontract of any tier entered into or executed for or in connection with the performance of that contract."

Section 2, paragraph (g) should be revised as follows:

"(g) The term 'made,' when used in relation to any invention, means the first actual reduction to practice of such invention in the course of or under the contract."

We think these changes should be made in the interest of clarifying the term "contracts" and in accordance with what appears to be the desire to reinforce contract provisions intended to insure that the U.S. Government receives all that it pays for in connection with Government research and development contracts. However, by the same token, we feel that this is a two-way street, and the Government should not get what it does not pay for. And at the same

time we might point out that the Government does not, in general, pay for the facilities (e.g., buildings and equipment) that the contractor has assembled, nor the expenses involved in obtaining and retaining the services of a highly skilled staff, nor the detriment to the contractor in losing the services of that highly skilled staff during the time that the contract is being performed on behalf of the Government.

Furthermore, in advocating revision of section 2(g) as indicated, we feel that inasmuch as the Government does not pay the contractor for ideas conceived prior to performance of the contract, by the same token the Government should not retain title to ideas merely conceived in the performance of the work. To guard against the possibility that the contractor will withhold or conceal useful or good ideas, and not disclose them to the Government, we propose to require at a later point in the bill that the contractor disclose to the Government all conceptions made during the performance of the contract work so that an evaluation of those can be made, and if the Government desires to go forward and reduce them to practice with Government funds, the contractor can be so notified; but in that event, the contractor shall have a royalty-free, nonexclusive license, with the right to sublicense others, should such conceptions be reduced to practice by the Government and later patented.

Section 3(b)(1) should be amended to read as follows:

"(1) Require the prompt and full disclosure by the contractor to that agency of any invention conceived or made in the course of or under the contract; and in the case of any invention conceived but not actually reduced to practice in the course of or under the contract, the contract shall provide that the Government shall, within 90 days after receipt of the information concerning such conception, inform the contractor of the Government's desire to actually reduce such invention to practice with Government funds;

Provided further, That in the event the Government fails to accomplish actual reduction of such invention to practice within 3 years after receipt of said report, or if the Government does not inform the contractor of its intention to actually reduce the invention to practice, and in either event, the contractor shall actually reduce such invention to practice using his own funds, then all right, title, and interest in and to such invention shall accrue to the benefit of the contractor; and both the Government and the contractor shall preserve information relating to such inventions in secrecy until the title thereto has been determined."

Section 4(a)(1) should be revised to read as follows:

"(1) The sole purpose of the contract is to create, develop, or improve products, processes, or methods which are intended for commercial use on a royalty-free basis by the general public; or required for public use by governmental regulations."

This revision is suggested in the belief that when the United States undertakes research and development work on products, processes, or methods which are intended for general public use commercially, this should be the stated and prime objective, so that prospective contractors will know if their business interests would be jeopardized by performing the contract work.

Section 4(b), in the portion on page 8 of the bill as introduced, line 5, after "position", should be changed to read:

"The agency head shall acquire no greater rights than the nonexclusive license specified in section 3(b)(2) unless he determines, after the invention has been identified, that there are in existence special circumstances, based on relevant evidence of record, which establish beyond a reasonable doubt that the public interest would suffer as the result of the contractor retaining the principal or exclusive rights in such invention."

The change is suggested on the basis that agency heads should not be put in the position of making a determination on the basis of speculation or the fear of criticism if their decision is to retain rights greater than a nonexclusive license on behalf of the Government.

Section 4(c) should be rewritten as follows:

"(c) As to any contract executed under this act, the determination of rights in any invention made by the contractor in the course of or under the contract shall be made by the agency head at the time of contracting."

It is believed that the postponement of determination of rights in patents can serve no useful purpose, and will only increase the cost to the public of Government research and development work. It may well be noted in this

connection that the United States may, at its election, acquire and use any invention for governmental purposes, regardless of patent rights and their ownership, at any time, and whether or not such patent is granted on an invention made in performance of a Government-sponsored contract (28 U.S.C. 1498).

Section 9, paragraph (c), should be revised to read as follows:

"(c) The number and general nature of such inventions with respect to which the agency has acquired greater rights than a royalty-free license in accordance with section 4, and a summary of the findings of fact upon which such determinations were made."

The change is suggested in order to provide the same type of review of actions of agency heads in connection with acquisition of rights greater than a nonexclusive license, as is required in the case of acquisition by the agency of rights no greater than a royalty-free license.

We thank you for the opportunity of expressing our opinion regarding proposed legislation.

Cordially yours,

WILLIAM H. ABBOTT,
General Counsel and Vice President, Legal Affairs.

NATIONAL SMALL BUSINESS ASSOCIATION,
Washington, D.C., July 20, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: In response to your invitation to submit additional material bearing on the issues involved in connection with the patent policy matters reflected in S. 789, S. 1047, S. 1809 and S. 1899, bills being considered by your committee, we are submitting the following additional comments and the enclosed studies, with the request that they be incorporated into the record of your proceedings.

REFUTATION OF SENATOR RUSSELL LONG'S ARGUMENTS

(*a*) Senator Long has made a great point that much of the Government's agencies and programs are already covered by existing legislation and "require title on behalf of the public." The fact that practically all of this legislation was accomplished through the use of the "rider" technique, whereby the legislation was passed without any significant discussion of the issues, without resort to committee hearings, and in most cases by voice vote without the presence of any substantial number of Senators, smacks of subterfuge in attempting to establish public policy without the knowledge, to say nothing of the concurrence, of a major portion of the Senate. On practically every occasion where the Senate has been permitted to cast a meaningful vote on the issue, the Long amendment has been defeated. What the legislation reported by this committee should seek to accomplish is to arrive at a fair, studied, and impartial determination of entitlement to commercial rights to Government-funded R. & D. inventions as well as the Government's entitlement to the fruits of privately developed inventions.

(*b*) Senator Long has attacked some aspects of international patent pooling which causes unfavorable international market conditions for American manufacturers. This is a variation of the attack on patents because of the antitrust implications of the limited monopoly conferred by patents. There is a simple answer to these "horrible examples"—enforcement of the antitrust and other laws which are intended to prevent these abuses. Cutting down private rights to patents, as we have previously stated to this committee, will at the most only inconvenience the larger firms, but for much creative small business will be a matter of life and death.

(*c*) In his defense of his position, Senator Long continuously muddies the water by equating consumer-oriented research such as that conducted by the Department of Agriculture and by HEW with defense and other nonconsumer-oriented research. The statement that "there is no risk in finding a market for the new product" is certainly true for new inventions completely developed for

the consumer market—but the exact opposite is true for most inventions with potential commercial application derived from defense, space or atomic energy research. The costs of developing a commercially suitable product from the bare R. & D. invention are almost invariably great. Senator Long is dead wrong when he says that the primary interest of contractors in obtaining commercial patent rights is to permit them to obtain "monopoly" profits. Classical "monopoly" pricing simply does not exist in the current marketplace, for a number of reasons well known to economists and most Congressmen. Of course, every businessman seeks to maximize his profits, but the primary reason for businessmen desiring to acquire patent rights is to insure that there is a reasonable prospect of recovering development costs and keep exclusive rights to manufacture the patented item to meet competition from substitute products. Without exclusive rights, the copier, who has not borne development and marketing costs, is in a position to undersell the developer—a grossly inequitable situation.

(*d*) One of the themes Senator Long keeps harping on is new industries which have grown rich on Government R. & D. starting from scratch in this field. I assume he means companies like Aerojet-General and TRW Co. (Thompson-Ramo-Wooldridge.) These are the examples of industries cited to which "billions of dollars of the taxpayers' rights have been given away." We do not believe that any significant inventions having commercial value have accrued to any of these corporations. They have grown rich on their research earnings. We call on Senator Long (as he is so fond of doing to those who do not concur with his point of view) to point to one instance of patent rights acquired by these corporations which have produced tremendous monopoly profits for these corporations. If cases exist where such valuable rights have been acquired we would also like to know how much private capital has had to be invested to market these inventions. (Parenthetically, no one in industry is seriously suggesting that these R. & D. based corporations really have any entitlement to R. & D. patents.) But even in the less extreme cases—the large corporations with many years of experience in a field of technology—we would be interested to hear of some of the horrible examples where the taxpayer's rights have been given away; where large corporations have acquired patents which were the basis for huge monopoly profits. We believe that since most advanced technology is interrelated, large companies with large patent portfolios as a matter of practical necessity must pool or cross-license patents, so that the only competitors likely to suffer are the small companies. Effective price competition between large firms who cross-license or pool patents is obvious in the everyday experience of everyone of us—the electrical appliance industries, automobiles, electronics, just to name a few. The conspicuous success stories in modern industry are those involving privately produced inventions mostly by small business which have prospered and grown—the Polaroid, Xerox, and Data-Control type of industries. We want to see more of these develop whether the patents are derived from private or Government funded research, and we want these patents made available to the small creative individual or business rather than in the hands of Government bureaucrats, even if it means that larger businesses will thereby also obtain the same rights. This course is in the public interest.

(*e*) Assuming without admitting that every argument made by Senator Long is logically correct, we believe that it is nevertheless in the public interest in most cases to give commercial rights to patentable R. & D. inventions to the contractor or inventor for the following economic reasons:

1. We know of no field in which a true classical monopoly can be obtained in the current consumer market; true monopoly pricing cannot be practiced in the present market for the following reasons:

a. There are always available substitutes which even if not as good as a desirable patented article, will restrict the seller in pricing—as the price of the patented article vis-a-vis substitutes gets out of line, the utility of the substitute increases in the mind of the consumer. A good example is the Polaroid camera and Polaroid film. Most photographers will agree that instantaneous processing of film has some highly desirable advantages; nevertheless, the utility of the product to the consumer is not so great that Polaroid products are disproportionately priced as compared with Kodak or other cameras and photographic supplies. This is the common situation in the marketplace. Monopolistic competition in consumer product lines is the rule rather than the exception. Patents are only one of a number of monopolistic elements which enter into distinguishing products and maintaining monopolistic competition—other factors are trademarks,

name brands, advertising claims, artistic (as opposed to functional) variation, packaging, geographic limitation of distribution and variations in quality. In many products where patents exist, patent claims or rights are the least distinguishing elements of competition, particularly if the market is dominated by a few large businesses.

b. The realities of large-scale production and consumer demand require that any product where the consumer exercises a choice between competing desirable expenditures must be rationally priced in regard to its utility. For example, we would probably all agree that a device capable of recording television programs for later reproduction, similar to the audio tape recorder, is very desirable and would command a large market. Assuming that a relatively inexpensive device were developed and were patented, what pricing policy would be adopted by the manufacturer? Obviously the price would have to bear some reasonable relation to the market. It would be a monopoly price but not in the classical sense. In the light of our knowledge of market demand and current pricing of television sets and audio tape recorders, we would conjecture that a video recorder would have to be priced under $500 to sell in quantity production, and to generate substantial profits. This is certainly not the classical monopoly price.

2. The proposed Federal Inventions Administration would certainly cost the taxpayer a great deal of money—probably much more than returns from commercially utilized inventions could ever hope to return in license fees and royalties. Costs to policing patent rights on the part of the Government involving court actions would be tremendous. Returns from nonexclusive licenses, even assuming a willingness to pay a fair royalty (not more than 1 percent of manufacturer's gross selling price) would be very low. If exclusive licenses are to be granted, disposal by public bid would be the only way to avoid favoritism and corruption in the administration. Most of the patents would probably still end up in the hands of the original developer with only nominal returns over costs of administration.

3. The tax aspects of patent exploitation by corporate developers are such that all profits would be subject to corporate taxes of 52 percent, plus taxation of dividends at individual rates. Much of the profit from private development in any event accrues to the Government in the form of taxes. Additionally the property rights in patents in many jurisdictions are also subject to property taxes.

4. In those few cases where an illegal monopoly is created the antitrust laws provide adequate remedies. Monopoly practices, including unfair pricing, may be reviewed by the FTC and the courts, and in extreme cases the courts can order licensing of patents or placing them in the public domain.

5. The labor implications of the course proposed by Senator Long are startling—to the extent that any policy restricts development of commercial applications, new employment opportunities are lost; but to the extent that U.S. patents are placed in the public domain foreign countries are free to copy (and even patent in their own countries) and using the fruits of U.S. skill and technology to produce and import the items into the United States to compete with our own sources of supply, and take away the jobs of American workingmen as well as the businesses which create them. U.S. patents give exclusive rights to the American manufacturer in the U.S. market and allows U.S. citizens to file for the foreign patents. Furthermore, under the McClellan bill, S. 1809, if a patented R. & D. invention is not practiced, the Government can force licensing or other disposal of the patent.

6. Commercial rights to patentable inventions developed by small business or individual inventors should accrue to them where they are to be used as capital for new business or to enhance existing small business.

7. Value of what is "given away" should be carefully appraised in the light of following considerations:

(*a*) In the commercial market the royalty value of a patent assigned or licensed to a manufacturer is usually in the neighborhood of 5 percent, seldom as much as 10 percent of gross sales, because it is generally recognized that marketing know-how and product development are the most important factors in selling a new product.

(*b*) The patent holder must guarantee the validity of the patent.

(*c*) The patent owner must agree not to compete or use his know-how for competing applications.

8. A prime purpose of certain proponents of the "title" theory may be to further weaken small- and medium-size creative industry, recognizing that the

strong middle class is the bulwark of our free enterprise system. The desirable alternative in the minds of these proponents is large industries controlled or owned by Government.

COMMENTS ON STATEMENT OF MR. JOHN M. MALLOY (DEPUTY ASSISTANT SECRETARY OF DEFENSE, PROCUREMENT)

We are shocked by the continued callous disregard of the Department of Defense of the real dilemma and hardships faced by the small business patent holder under existing law and procurement regulations, as shown by the comments of Mr. John M. Malloy on S. 1047. When we balance the simple inexpensive and effective procedure which would be set up under S. 1047 for permitting Government infringement of private patents where needed for national security, against the impossible situation now faced by small businessmen in trying to protect their patents and obtain fair compensation for their use, we are dismayed that any Government official who is aware of the realities of the two situations could reach the conclusions of Mr. Malloy.

Certainly none of us is trying to deny the Government the right to produce items urgently needed for national defense whether patented or not. S. 1047 would not in any way permit this result by injunction or otherwise. If the patented item cannot be fairly obtained from the patentee or a licensed source all that is required is a simple finding by the Secretary of Defense that national security requires infringement—this power could even be delegated to contracting officers if deemed desirable. What we seek to accomplish by supporting S. 1047 is to change current attitudes and philosophy which now practically require contracting officers to induce infringement of any and all patented items. We wish to see a reestablishment of a requirement where national security permits of purchasing patented items from licensed sources or, if they are unfairly priced, of purchasing acceptable substitutes. We also seek to reestablish a climate where procurement officials will fairly seek to obtain licenses for use of patented items and, where appropriate, pay fair royalties for such use. At present the legislation which permits acquisition of such rights might just as well be repealed for all the likelihood of any procurement officer now seeking to purchase patent rights. We must reiterate that for creative patent oriented small business reestablishment of a fair basis for dealing with the Government is mandatory if any substantial segment of such industry is to survive to serve the Government's needs.

Certainly, Mr. Malloy must have had tongue in cheek when he said, "removal of the power to secure an injunction against Government procurement does not deprive the patent owner of reasonable compensation for the unlicensed use of his patent. An action against the Government lies in the Court of Claims, and meritorious claims may be settled there. Under 10 United States Code S. 2386, the military departments are authorized to settle infringement claims administratively before the suit in the Court of Claims is brought."

We have pointed out and have numerous examples showing that for small business (the primary suffered) a suit in the Court of Claims is no remedy at all because of its cost and the delay involved. Furthermore, administrative settlement of claims cannot be made, under GAO rulings, in the common case where there is an indemnity provision in the infringer's contract and the infringer refuses to settle. All the cards are stacked against the small patentholder.

We further take issue with Mr. Malloy's statement—"The Department of Defense does not encourage unlicensed use of inventions as a matter of course * * *." This may be true as a matter of "top-drawer" policy, but the realities of the DOD procurement situation are that procurement officers not only consciously use every means overt or surreptitious to acquire proprietary designs, but to an extent aid, abet, and induce involuntary infringement on the part of suppliers.

We think that Mr. Malloy has confused the issue in regard to the real effect of S. 1047 by his studied harping on the injunctive remedy which lies in the background of this bill—the real purport of what has been said is that, from the standpoint of the DOD bureaucracy, it is much simpler to continue the passive state of affairs giving carte blanche to DOD officials and letting us small businessmen (who seem to be such a thorn in the side of DOD) continue to try to grapple with this impossible legal and administrative situation, rather than have his own people have to make the simple determination, in

appropriate cases, that national security requires infringement of a patent. If our defense administrators are incapable of reaching the simple judgment that a hat rack or a radar component do or do not involve national security, we better get a new team. The statement that making such determinations would delay Government procurement, in our view, is sheer nonsense and serves the same ends.

The end of achieving competitive pricing for patented items having no national security impact is also sheer nonsense in our estimation. No producer of nonessential items, patented or not, can impose "classical" monopoly prices on his product. Available reasonably priced substitutes tend to keep prices of all patented products at a reasonable level. Furthermore, the Government's broad know-how and coercive powers in the field of negotiated procurement are sound and sure means of keeping prices in line. We most earnestly ask the committee to examine closely the reasoning of DOD and to reject it by reporting some version of S. 1047; power to make determinations should be vested in the "head of the department or agency concerned" rather than in the Secretary of Defense to overcome the objectionable feature of having procurement actions of other departments or agencies reviewable by the Secretary of Defense.

COMMENTS ON STATEMENT OF J. EDWARD WELCH, DEPUTY GENERAL COUNSEL, GAO

The views expressed by Mr. Welch follow what is, in our view, a time-honored tendency on the part of the Comptroller General, in his excessive zeal to protect the public interest and interpret the will of Congress, to be pennywise and pound foolish. The real costs to the Government in terms of shoddy goods, costs of administration, legal expenses, and loss of indemnity rights which are part and parcel of patent infringing procurements are never included in GAO calculations. (But it is interesting to note that GAO was able to derive the startling proposition that by payment of ordinary business overhead in its procurements, the Government somehow is financing contractor's private research programs. Is the Comptroller General so naive that he fails to appreciate that all private research is ultimately charged off against goods sold, or does he believe that private research funds are provided by some genie or philanthropist?)

Mr. Welch blithely skips over the most important question of public policy which the Congress is being asked to validate or refute in the legislation which will be reported out by this committee—namely, shall we continue to support the private, free enterprise system through our patent laws, particularly as they encourage the establishment, proliferation, and success of the creative small business, or shall we retreat further into state socialism where everything either belongs to the Government or is effectively controlled by Government bureaucracy?

The very issuance of the Comptroller General's opinion of October 6, 1958, B–136916, interpreting the Defense Procurement Act in such a manner as to prohibit the then prevalent procedure of procuring patented articles by negotiation, served to repeal, for practical purposes, the authorization contained in 10 U.S.C. 2386 for the Government to purchase rights in patents. Again, as in the case of the Department of Defense witness, when Mr. Welch states that the patentholders rights are "preserved to a substantial if not complete extent by rights to reasonable compensation preserved in section 1498 of title 28 United States Code," he simply is not aware of the inadequacy and unfairness of the small businessman having to resort to this proceeding. We believe that a fair appraisal of total real costs to the Government would show that negotiated procurement of patented items from licensed sources would in the long run be cheaper and more equitable to all parties concerned. S. 1047 provides a mechanism to accomplish this purpose and still permit purposeful infringement by the Government where there is a national defense purpose for the procurement and supply from licensed sources is inadequate for any reason.

STUDY PREPARED FOR NSBA BY DR. BARKEV S. SANDERS

We have asked Dr. Barkev S. Sanders of the Patents, Trademarks, and Copyright Institute of George Washington University, Washington, D.C., to prepare for us a study of certain aspects of patent policy as they relate to small business. We asked Dr. Sanders to do this for us because we were aware of the tremendous background which he has acquired in this area in connection with previous statistical and analytic studies of the patent system.

The conclusion reached by Dr. Sanders in the enclosed study which were of particular interest to us, since they support and document some of our previous statements and recommendations to the Congress, are as follows:

(1) The value of patents to individual inventors and small business is very great.

(2) A very large proportion (50–60 percent) of patents developed through private effort and investment is actually used for commercial purposes.

(3) The allegation that there is widespread suppression of patents by corporations has not been verified by documented studies. On the contrary, it appears that unused patents are unused primarily because of economic considerations.

(4) Patents are more intensely exploited by small business than by large.

(5) Individual inventors and the small business sector continue to make a significant contribution to the advance of knowledge, invention, and patenting of inventions.

(6) The quality of patents applied for and issued, as attested by utilization, is increasing.

(7) Comparatively few patentable inventions result from Government R. & D. contracts.

(8) Inventions have little intrinsic commercial value in the hands of the Federal Government.

(9) The proportion of patents developed with Federal R. & D. funds put to commercial use is much smaller than for those developed with private funds.

(10) Companies engaged in federally financed R. & D. are usually not those with the highest skills in the area of development sought.

(11) The Government should waive all its commercial rights to patentable inventions because this would result in more commercial exploitation of economically worthwhile inventions.

We believe that the data provided by Dr. Sander's study will be valuable to the committee because it brings together much of the available statistical data regarding patent exploitation by business.

EXAMPLES OF GOVERNMENT INFRINGEMENT ACTIONS AGAINST SMALL BUSINESS

We are submitting as an attachment to this letter a compilation of complaints which have been assembled by our association, to present dramatically exact fact situations covering Government actions complained of by small business. I am asking the committee to delete the names of the complainants and other corporations referred to in the complaints, for a number of reasons—fear of reprisal, pendency of litigation, etc. We feel that these reported incidents which represent only a handful of the numerous complaints which we continue to receive should stir the committee to take appropriate action to incorporate some relief similar to S. 1047 in whatever legislation it reports to the Congress.[1]

In conclusion, we wish to express our appreciation for the opportunity to present these additional comments to the committee.

Very truly yours,

HENRY J. CAPPELLO,
Consultant on Patent Policy.

NEISLER LABORATORIES, INC.,
Decatur, Ill., August 25, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Subcommittee of Patents, Trademarks, and Copyrights, Senate Judiciary Committee, Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: Reference is made to hearings held by your subcommittee on S. 789, S. 1809, S. 1899, and S. 2326.

Aware of hearings scheduled by your committee for August 17, I had requested an opportunity of presenting a statement at a later date inasmuch as it was physically impossible for me to be available on the 17th. In a letter of August 10, your chief clerk, Mr. Steven G. Haaser, graciously suggested that should I so desire it would be acceptable to submit a statement for inclusion in the record.

[1] Material contained in committee files.

Toward this end, I have prepared a written statement which I would like to respectfully submit for consideration by your subcommittee for inclusion as part of the record pertaining to hearings on these bills. The statement is submitted in duplicate and I trust that it is in proper form for consideration by your subcommittee.

Respectfully yours,

C. J. CAVALLITO,
Director of Research.

STATEMENT OF DR. CHESTER J. CAVALLITO, DIRECTOR OF RESEARCH, NEISLER LABORATORIES, INC.

My name is Cheser J. Cavallito; I am currently director of research, Neisler Laboratories, Inc., Decatur, Ill. Until a few months ago, our company operated as an independent concern in the pharmaceutical industry. We are now a subsidiary of Union Carbide Corp. Throughout the period of almost 15 years that I have been with the company, we have been engaged in creating and marketing new drugs.

My personal qualifications are set forth in appendix A to this statement.

The above bills relate to the vitally important subject of rights to inventions made in connection with Government-financed research. I do not propose to discuss the provisions of the bills. Rather, I would like to present to you some of the facts relating to research in the field of new drugs, based on some 25 years of experience in this field. These facts, I beleive, show beyond question that the public interest is jeopardized by any legislation that would (1) impair the full and complete interchange of information and cooperation between academic and institutional scientists and industry research personnel or (2) remove the patent incentive in connection with the research and marketing of any new chemicals having possible drug utility. But before detailing these facts, let me discuss my general observations in more detail.

As I understand the situation, it is agreed by all concerned that the results of Government-financed research should be made available to the public to the maximum possible extent. The only question is how this can best be accomplished. Some have taken the position that where the Government pays for some part or all of the activity leading to an invention, there is some form of giveaway if the contractor (or, indeed, any private enterprise) is given ownership of the patent rights. One fallacy of this approach lies in the assumption that the contractor (or other private enterprise) acquires some sort of presently existing and commercially valuable right in a new product. At least in the drug industry this is not so. There may, indeed, be some patent rights or prospect of patent rights in a product that shows some promise of drug application and some indication that it might survive the long period of development and marketing before any return on investment is made. But there is almost never, if ever, a drug invention made during the course of Government-financed research that is carried to the point of commercial practicality at Government expense.

This is not due to any inadequacy of individuals engaged in Government-financed research. My experience—and I believe the experience of others who have observed the activity—is that the personnel involved do their best to give the Government full value for its money under the conditions they face. The missing ingredient is one that the Government never has supplied in the past and I do not believe can supply in the future. This is the spirit of enterprise. Unless there is a strong incentive to take risks nobody will do so. And without the risk taking, drugs cannot reach the point of practical application. Indeed, the risk taking required in the drug industry is probably greater than that of any other substantial industry.

Where Government patent ownership is not involved, our patent system is a vital factor in attracting risk effort inthe development of new drugs, and thereby improving our health. It also makes possible the publication of research findings and the interchange of scientific knowledge that vastly increases the rate of our scientific progress. The U.S. patent system is particularly strong. Without it, it is highly unlikely that the United States would have developed the world's strongest and most productive pharmaceutical industry. Of some 587 new single chemical drug entities that became marketed drugs between 1941 and 1963, 355 originated in the United States. U.S. firms accounted for 321 of these.

This record, I am sure, reflects the fact that a concern in the U.S. drug industry has a very strong incentive—through the patent system—to make the successive risk investments required to bring a drug to the point of practical application and usefulness to mankind.

To the extent the patent system does not apply as to a particular drug, this incentive is lost. Where the consequence of Government-financed research is a curtailment of available patent rights, the effect of the patent system as a stimulus to these risk investments is reduced, or even lost entirely. The spirit of enterprise is no longer fully effective as to such drugs. Their potential may never be realized because of lack of incentive to perfect and market them.

The patent system can be rendered ineffective as to a drug by Government-owned patent rights that are simply thrown open for use by anyone. It can also be rendered ineffective by premature publication disclsoure of the chemicals, which curtails available patent rights.

The history of drug developments supports a conclusion that it is necessary—as a practical matter—to have the strongest possible patent rights for new drugs. Any Government activity that curtails such rights may result in potentially important drugs remaining unexplored and never carried to the point of practical utilization for the benefit of mankind. The policy of the Government as to Government-financed research activity, may curtail possible patent rights by impinging upon the new drug development activities of a pharmaceutical concern at any one of many points in the long road from an idea to a perfected, marketed, drug. In essentially all practical cases, the extent of the Government investment in the particular product is small—especially in relation to the inventment required of the pharmaceutical company in further research and marketing of the drug. To show why this is so I devote the next portion of this statement to a general description of the steps required to carry a drug to the point of practical benefit to mankind, with emphasis on the risk decisions that must be made and on the occasions where Government-financed research activities may be involved.

The elements of risk, the decisions that must be made, and the particular capability of a business enterprise operating under incentives to make the decisions and thereby take the risks, is best brought out by tracing the history of a drug to the point at which it is available to the public. In so doing, I shall bring out both the work and contribution of the employed personnel of the business concern and the work and contribution of academic personnel who frequently play an important role in the overall sequence of events. Within the limits of this statement it is not possible to do more than state in general terms the various procedures and steps in making a drug available for practical use in medical practice. But the sequence set forth is present in nearly every case, including particularly the steps from idea to invention to commercial product. It should be added that it takes more than an idea to make an invention; it takes more than an invention to make a product; and it takes more than a product to make a drug commercially available where it can be used by mankind.

MAKING THE INVENTION

The first step in the long road to a new drug of use to mankind is the invention. For a new synthetic drug (that is, new chemical compound useful as a drug) the work begins with the idea or concept of the new chemical structure or structures, followed by devising a way of making them. For a new drug derived from a natural source, the work begins with the idea or concept that some natural plant or animal material may contain a material useful as a drug, followed by devising a way of testing, isolating, determining the structure and possibly synthesizing the active substance or substances. Under today's conditions, these steps are becoming increasingly more difficult and require much more vision and ingenuity than may appear—for the less difficult and more readily apparent drug leads have been pursued by others in the past.

In the case of a chemist in a pharmaceutical company laboratory, he is usually using his scientific knowledge and experience intuitively conceiving or visualizing new chemicals with a hoped-for, specific, biological property of potential value in medicine. Having so visualized the chemical (which may be a new synthetic chemical compound or some derivative of natural plant or animal material), he then proceeds to devise ways to make it.

In the case of an academic scientist, possible new drugs (whether new synthetic chemical compounds or derivatives of natural plant or animal materials)

are conceived predominantly in the interest of advancing scientific knowledge or a part of a teaching program. The academic scientist may or may not be interested in the potential biological properties of the substance. Many academic chemists, for example, are totally uninterested in such properties. An academic chemist in the chemistry department of a college of pharmacy, however, is usually interested in biological properties. In the case of an academic biologist, such properties are of major interest.

But whether the interest is only one of chemistry, or is also a matter of possible biological properties, the product envisioned must be made. In the case of some possible drugs, such as those in the sulfa-drug group, this may not present great difficulties. In the case of other drugs, such as some steroids and antibiotics, it may be exceedingly difficult to make the product. In many instances an academic scientist is at this point compelled to obtain the help of others. Frequently such help is obtained without cost from a pharmaceutical concern having experienced personnel and facilities for conducting unusual chemical processes.

After the product has been made, it is still necesary to demonstrate biological activity before there is a drug invention. This procedure is usually carried out quote differently in the laboratories of a pharmaceutical concern than in the case of a product originating in the work of an academic scientist. In the laboratory of a pharmaceutical company, the chemicals having potential drug activity are distributed to scientific specialists such as physiologists, pharmacologists, biochemists, endocrinologists, microbiologists, immunologists, or others having the skills and facilities to determine the presence of biological activity. These scientists conduct tests in the laboratory on experimental animals or living systems using test methods in which the performance of known drugs is recognized. They also look for any novel or unusual response that might suggest a new or unpredicted biological effect and possible application of the chemical. An important part of the work of these scientists is devising new testing procedures capable of detecting biological activities not previously subject to test or of improved responsiveness and reliability as to biological activities covered by previously available tests.

In the case of an academic scientist, biological testing is necessary to make a new drug invention just as in the case of the company scientist. However, in many instances an academic chemist is not interested, or only mildly interested, in biological properties. In such instance he will cooperate with a pharmaceutical concern interested in testing the products he has made, but will do nothing more to bring such testing about. Where the academic scientist is decidedly interested in biological properties, he may have facilities available to make such tests, in which event they are likely to be carried out. More frequently, however, he either has no facilities for this purpose or he needs more elaborate facilities than are available at the institution. In this instance the academic scientist must again turn to the laboratories of a pharmaceutical concern.

At this stage—making the invention—Government policy has a great influence on the extent products of possible biological activity are tested by pharmaceutical concerns. Usually the academic scientist who visualizes and makes the chemical compound (or other product) is working on some Government-financed research. This may be the very research that led to the making of the compound or other product. Under present provisions in many research contracts, the Government is believed to have full patent rights to such products, regardless of the contribution of a pharmaceutical concern in actually testing. This has forced pharmaceutical concerns in most instances to refuse to conduct such tests—for the only value of such tests to the concern is in leading to a drug which can be marketed under patent protection that will protect the necessary investment. It is essential, therefore, to have some way to provide reasonable patent rights to the pharmaceutical concern if the potential value of the products made by the academic scientists is to be realized in terms of drugs available for use.

It should be noted that in this instance there is no question of giving something away to a Government contractor who already receives compensation for services. The pharmaceutical concern receives no compensation from the Government in any event. In the past, the concerns have entered into patent agreements under which the concern obtains some exclusive rights sufficient to justify the initial biological testing and further drug development and marketing expense. If academic scientists (or their institutions) working under Government

contracts are permitted to retain sufficient rights to enable them to grant some exclusive rights to pharmaceutical concerns, this practice can continue. Otherwise, there is every indication that it will soon come to a complete halt.

I understand from discussions with lawyers that a pharmaceutical invention is regarded as "conceived" when the chemical is visualized and its probable activity identified. I also understand, however, that in some instances the "conception" is not complete until activity is demonstrated—but that under these circumstances the conception may not be that of the person making the biological tests, but rather may be considered to be that of the person who visualized the product and its probable activity that is later demonstrated to exist. Since an invention is regarded as "made" under a Government contract when "conceived" during the performance of the contract, it is my understanding that where an academic scientist visualizes and makes a product while under such contract, the invention is likely to be the property of the Government even if a pharmaceutical concern invests far more than the Government in biological tests and other activities.

If the biological testing of one or more products shows some promise of useful biological properties, it is necessary to undertake very substantial additional research before a product that may be even tested on humans is obtained. This activity entails some very important and risky decisions. The first decision is that of identifying the family of chemicals that should be made and tested to be sure that the chemical having the greatest desirable activity and the least undesirable activity is found. This is not a simple task. Endless variations in chemical structure are usually possible. A skilled scientist may be able to identify the structural components of the chemical that contribute to the activity and suggest the chemical variations that can most productively be explored. More typically, it is necessary for the chemist and the biological scientist to work in close liaison in preliminary tests directed to identification of the biological effects resulting from variation of parts of the molecule. In any case, an extremely difficult decision must be made in determining just what products should be prepared and subjected to biological tests.

This decisional process is part of the new drug development procedures that a pharmaceutical concern is designed to follow. It is particularly suitable for a business concern spurred on by the prospect of an important new drug that can be marketed under patent rights. If the testing of related products stops short of testing the optimum product, the resultant drug will not be the best possible. But if the testing goes beyond the point of diminishing returns, investment is needlessly increased and availability of the drug to the public is needlessly delayed. Decisions of this sort are best made in the environment of a competitive enterprise where wise decisionmaking results in profits and unwise decisionmaking may be economically fatal.

MAKING THE PRODUCT

The first step in making a product from the invention is to select the compound from among those tested which seems to justify further development. Among factors influencing a selection at this point are: chemical considerations—such as difficulty and cost of synthesis on a larger scale, stability, physical form of the chemical, specifications, etc.; biological considerations—such as spectrum of biological activities, absorption, anticipated difficulties from toxicity or metabolic disposition; pharmaceutical consideratons—such as formulation problems that might arise in converting the raw generic substance from the chemist's bottle to a stable, reproducible, functional pharmaceutical dosage form. It readily can be seen that the potential sources of difficulty are numerous and multidisciplinary. If a poor selection is made, this will be an expensive error in judgment because all of the work would need to be repeated if another compound later had to be chosen.

After a new chemical is tentatively selected for further evaluation, it is put through the paces of additional safety testing in animals and elucidation of a more complete biological profile. This, if a new compound were turned up as warranting interest because of its ability to lower blood pressure in animals, prior to its first evaluation in man it would be necessary to determine what other things the chemical might do in a wide variety of biological test systems and to conduct additional preliminary safety and toxicity tests. At this point, one is still a long way from knowing whether his new chemical is a drug.

If the acute animal tests show now limiting undesirable manifestations, subacute toxicity tests in animals are conducted for about 3 months. If the compound passes this safety test, then one can consider very careful, preliminary, "dose-range" explorations in a limited number of human volunteers.

The decision to conduct enough laboratory tests to prepare a compound for preliminary evaluation in man involves the assumption of considerable decision-making risk in commitment of resources. Furthermore, the decision as to how much animal work to conduct prior to preliminary evaluation in man is a weighty responsibility for the research and general pharmaceutical management.

Additionally, the Food and Drug Administration requires that an investigational new drug application be filed with them prior to the institution of any evaluation of an experimental drug in man. The basic responsibility and the risks inherent to this step nevertheless rest, as they should, squarely upon the pharmaceutical company or submitter of such a new drug.

The first and preliminary evaluation in man involves studies which often do not tell us whether the new chemical is active in influencing the disease for which it is of possible interest. Rather, the early investigations are designed to guide subsequent studies from the view of how much of the potential new drug substance can be safely administered to man without inducing limiting, undesirable side effects. These preliminary tests generally are referred to as human "dose-range" studies. These are conducted in human volunteers and by at least two independent, clinical investigator groups. If the new chemical shows undesirable features at this stage, it is dropped from further consideration. As one can see, an appreciable investment has already been made in coming to this point of no further pursuit. If, on the other hand, the compound does not show undesirable characteristicts, it yet remains to be demonstrated that it is effective for the disease condition to be treated. Many factors now enter into the design of steps beyond this point.

If a drug potentially will be used as therapy for a chronic disease, it will be administered for prolonged periods of time. In these instances one must begin even more extensive, expensive, and time-consuming, long-range animal toxicity studies to determine the safe dose range of the experimental drug prior to its administration for a significant period of time to humans with the disease. It is self-evident that a drug for treatment of an acute condition such as pneumonia, which would require administration of the drug for a limited period of time, poses a different kind of safety problem than one for treating diabetes, for example, which requires a day in and day out medication for the remainder of the patient's life. The decision to proceed to long-range toxicity studies involves significant calculated risk in the investment of resources. The decision to pursue clinical testing beyond the initial dose range studies commits the company to possible expenditure of very sizable sums of money over several years' time. The company expenditures for clinical studies involve not just internal costs, such as maintenance of a medical department, preparation of clinical supplies, etc., but financial support for external studies by clinical investigators. These external clinical costs include grant supports to the institutions where studies are to be conducted and reimbursements for the large numbers of often expensive clinical laboratory tests used to monitor the effects of the drug on the volunteer patient. Investigators of high caliber sought to conduct clinical studies of this kind also may be carrying on other research programs for which some financial support may have come grom philanthropic sources, or from local, State, or Federal agencies. Total isolation or segregation of every aspect of every projects by an investigator on the basis of source of funds is virtually impossible. It would cut off from the industry the services of many leading clinical investigators if the proprietary position in the company's drug were to be usurped by the Government whenever any part of the investigator's or institution's support of a drug study were associated with Federal funds.

Here the policy respecting Government-financed research by academic scientists again impinges on the development and marketing of new drugs. The pharmaceutical concern must be able to use the facilities of the academic clinical investigator. It cannot do so if the consequence of using these is to lose the patent rights that are essential to marketing of the proposed new drug. While I do not believe that—aside from exceptional cases—any present practice relating to Government-financed research contracts threatens the pharmaceutical

concern in this respect, any continuation of the recent trend toward ever-increased Government claim of rights may well do so. If this occurs the consequences will be disastrous to new drug development and marketing.

After collecting considerable amounts of data from animals and from human clinical work with a new experimental drug, one usually has an accumulation of encouraging and discouraging information which requires evaluation. There is no such thing as an ideal drug. No drug is without some shortcomings or limitations. Yet, if we are to be practical and make step-by-step advances in medical therapy, we must make realistic compromises with the ideal and in light of the best medical judgment determine whether the evaluated data from a new drug shows sufficient advantages to outweigh its limitations and justify its use in treatment of a disease. The company management once again must make a high-risk decision. Do the overall characteristics of the investigational drug merit its market introduction as a product? Errors in judgment escalate in costliness as a drug development program moves closer to the product stage. A new drug application filed with the Food and Drug Administration may require several years to clear. During this time, the company has considerable money spent which earns no income and in practice, usually continues to spend money on additional studies. Finally, that rare day may dawn for a pharmaceutical company on which it receives approval of its new drug application. To reach this point, an average of 5,000 compounds were prepared, studied, and discarded by the industry before the one became an acceptable, marketable product.

CONDUCTING A PHARMACEUTICAL BUSINESS

Having a new product is an exciting situation for any company. This is particularly true in the pharmaceutical industry. Having a product, however, does not guarantee that it will form the basis of a profitable business. The company may be compelled to make a major investment in a new factory installation to manufacture the drug substance. Pharmaceutical production facilities may need to be designed or added for manufacture of the product. Quality control, packaging, distribution, and marketing efforts are required. These costs are particularly high during the early periods of new product introduction. To these costs and problems one must add the ever-present possibility the drug just won't be a market success for any of several reasons. Furthermore, in a highly competitive industry, who knows how soon and from what direction a new product will appear which overnight will make yours obsolete?

STEPS IN THE DEVELOPMENT AND MARKETING OF A NEW DRUG FROM THE NORMAL LIMIT OF GOVERNMENT-FINANCED ACTIVITY IN MAKING COMPOUND WITH SOME ACTIVITY TO FIRST MONETARY RETURN

There are, of course, endless variations in the sequence of steps leading to a marketable new drug. General indications of what takes place may nevertheless be helpful to your committee in visualizing what occurs. I have accordingly attached hereto an outline of steps in the development and marketing of a new drug. The outline extends only from the point at which a chemical is found to have an interesting biological activity to the time of first sale of the drug that ultimately results. The total elapsed time could range from 4 to 8 years. The total investment could fall in the range of from about $2 to $12 million. These are not absolute limits, but do represent the ranges usually encountered today. All of this investment must be made on a further risk basis in the light of the chance that a competitor will market an equal, or better, drug during this developmental period or shortly thereafter. The pharmaceutical concern must have patent rights to justify this investment.

The Government investment in a potential new drug rarely extends beyond the point where it has been made by an academic scientist and some biological activity shown to exist (a demonstration that usually occurs in the laboratories of a pharmaceutical concern, to whom the compound has been given for this purpose). If the matter is dropped at this point, there is no drug suitable for marketing. If the matter is pursued, as illustrated in the outline, millions of dollars must be invested before there is any return. Such investment cannot be justified without patent rights. The initial Government investment in the making of the compound—perhaps only $10,000—is far outweighed by the investment of the pharmaceutical concern. It follows that Government policy

should be based on leaving to the contractor in such instance sufficient patent rights to enable it to grant rights to the pharmaceutical concern adequate to support investment necessary to bring the product to the point of utilization to the benefit of mankind.

One product having some pharmaceutical activity as tested in biological laboratory. (For every such compound, pharmaceutical concerns make and test many compounds. Where an academic scientist has made the compound, he may fortuitously hit upon one with some activity. If the academic scientist has been supported by the Government to any extent, the support does not normally extend beyond the point of having made such a compound.)

Synthesis of 25–100 related compounds for test and determination of optimum chemical; $50,000 to $200,000 invested by company.

Biological screening of 25–100 compounds; $15,000 to $50,000 invested by company.

Full biological laboratory profile of compound selected as optimum; $50,000 investment.

Preliminary, 3-month, animal toxicity tests; $10,000 investment.

Metabolism and biochemistry studies; $50,000 investment.

Pharmacy research and development; $50,000–$100,000 investment.

Human dose-range studies; $15,000 investment.

Long-term animal toxicity tests; $60,000 investment.

Pre-new-drug application human evaluation of drug; $25,000–$1 million investment.

Processing of new-drug application; $100,000 investment.

Introductory supplies, production facilities, marketing; $5 million investment.

First sale and monetary return.

If drug is successful, and is not displaced too soon by an even better drug, the monetary return will be adequate to justify the investment made on the drug, together with investments made on unsuccessful drugs.

Total elapsed time from first compound with some activity to first monetary return: 4 to 8 years.

Total investment from first compound (and normal limit of any actual Government financed activity) to first monetary return: about $2 million to about $12 million.

APPENDIX A

STATEMENT OF QUALIFICATIONS, DR. CHESTER J. CAVALLITO

I received a bachelor of science degree in chemistry from Rutgers University in 1936. My doctor of philosophy degree was granted by Ohio State University in 1940. My field at this time was organic and physiological chemistry. In connection with work leading to the Ph. D. degree I also served as teaching assistant in the physiological chemistry and pharmacology laboratories in the medical school at Ohio State University.

Following receipt of my Ph. D. degree, I worked for 1.5 years at Goodyear Tire & Rubber Co. My work there dealt with the techniques for preserving food using synthetic polymer films such as Pliofilm as protective agents. After this I spent some 9 years at Sterling-Winthrop Research Institute, engaged in research work in the field of pharmaceuticals. Since January 1951 I have been director of research of Neisler Laboratories, Inc. (formerly Irwin, Neisler & Co.), of Decatur, Ill., which this year became a subsidiary of Union Carbide Corp.

I have served as secretary and as chairman of the Division of Medicinal Chemistry of the American Chemical Society and am a member of the editorial board of the Journal of Medicinal Chemistry. I have made presentations and have lectured in the filed of organic chemistry, drug mechanisms, and chemical pharmacology at meetings and at universities, both here and abroad. I have served as lecturer in the Department of Pharmacology at the University of Illinois College of Medicine. At present, I am serving on the Chemical Advisory Board for Walter Reed Army Institute of Research. I have authored approximately 70 scientific publications, and have received over 30 U.S. patents.

I am a member of Phi Beta Kappa and Sigma Xi honorary fraternities. In addition to the American Chemical Society, I am a member of the Chemical Society (London), the American Association for the Advancement of Science, the New York Academy of Science (fellow), and the American Society of Microbiology.

NEW JERSEY PATENT LAW ASSOCIATION,
Newark, N.J., May 28, 1965.

Re hearings June 1 and 2 on Government patent policy.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: The New Jersey Patent Law Association has reviewed the provisions of S. 1809 and S. 1899 which are to be considered by your committee at the hearings to be held next week. Our association believes that your bill S. 1809, the Federal Inventions Act, is a very statesmanlike handling of this extremely important subject.

In the opinion of our association, S. 1809 is an excellent bill which provides full safeguards to the Government and the public while permitting a degree of flexibility to the Government agency head to administer the patent rights provisions in Government contracts to best serve the public interest.

We believe our national policy must be flexible because of the diverse types of Government research. In some cases where a field of research has been wholly Government funded and the contractor brings no private background to the contract work or where the research objective is to develop items for use by the public, for example, civil defense or public safety equipment, Government retention of title to Government-sponsored inventions may be desirable. In other cases where the research is primarily directed toward governmental activities but the Government wishes to encourage, but not support, future development in commercial areas, granting greater than nonexclusive rights to a contractor may be essential to encourage later private development.

We believe that to develop commercial uses at private expense of most inventions requires more than nonexclusive rights for the person who is to make the developments. Extremely large sums of money are required in most instances to develop a new product to its commercial stage. Only if a company can recover its development expenses and have some hope for a reasonable profit on the products which it sells, will it be willing to take the great risks involved in attempting to commercially develop a new product.

We believe that S. 1809 accomplishes the desired objectives of fully protecting the Government on inventions developed under Government contract yet at the same time, it gives a flexibility which will permit and in fact encourage, contractors to develop for commercial uses inventions which may have been made under or in connection with a Government contract.

We have two minor suggestions, however, which we should like to have considered in connection with S. 1809. Section 2(g) appearing on page 3 of your bill, defines when an invention has been made. We believe that the words "in the course of or under" the contract could be misinterpreted to imply that inventions made during work performed by a contractor not under the contract but which may be in a related field should be considered as coming within the definition when an invention is made. We believe that this could be clarified by changing the words "in the course of or under" to "in the performance of work called for or required under." Without this clarification, a contractor might be inclined not to accept Government contracts in fields in which he is already doing commercial work (which fields, of course, would be where he would have his greatest capabilities).

Our other suggestion regards section 4(a)(2) on page 7 of your bill. It refers to contracts for exploration into fields which directly concern the public health, welfare, or safety, and we believe it could be misinterpreted by contracting officials as applying to almost any contract which the Government might award. Almost anything which the Government gets involved in does in one way or another directly concern the public health, welfare, or safety. Therefore, we respectfully suggest that this section be expanded by setting forth those specific types of contracts which you would feel directly concern the three broad categories referred to in section 4(a)(2). Thus, for example in the field of public health, illustrative examples of such contracts would be those for developing means for curing and preventing diseases, matters related to sanitation and sanitary facilities, and improved food products for use by undernourished segments of our population.

In closing, our association wishes to thank you for your efforts in endeavoring to develop a national patent policy which will be fair and equitable both to the Government and Government contractors. Also, we wish to thank your committee for considering our statement on this matter.

Respectfully yours,

JULIUS J. DENZLER, *President.*

THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK,
New York, July 16, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: The Committee on Patents of the Association of the Bar of the City of New York, being charged to examine pending patent legislation and authorized to promote or oppose it on behalf of the association, has given consideration to the three bills now pending before your subcommittee on the subject of Government patent policy with respect to inventions under contracts relating to research and development, such bills being S. 789 (Saltonstall), S. 1809 (McClellan), and S. 1899 (Long).

As a result of such consideration, our committee has approved S. 1809 (McClellan) and urges the passage of this bill. The committee wishes to register on reservation, namely in feeling that the concluding sentence of section 4(a) should be clarified to avoid future interpretations of this provision (by Government agencies) which might, for all practical purposes, foreclose the application of such provision in the principal areas where exceptional circumstances may arise.

In general support of the bill, the committee recognizes that there are important reasons for enactment of a law prescribing Government patent policy in all fields of research and development contracts. The committee further recognizes that in support of S. 1809, there are very cogent reasons for permitting a division of rights, between the United States and the contractors, as to inventions arising under contract operations, and in particular for permitting the title or principal rights (saving always a license in the Government) to be acquired by the contractor in a number of appropriate circumstances, in contrast to proposals, as in one of the other pending bills identified above, that would essentially vest all rights in the Government, with relatively little exception even as to a license in the contractor.

Some of the reasons for favoring a balanced policy such as understood to be intended in S. 1809, including provisions allowing the contractor to acquire greater rights than a mere license with respect to the contemplated inventions under appropriate circumstances, are predicated on the concept that the incentive values of the patent system, relative both to the interest of the Government in getting maximum results of research and the interest of the public in getting the benefits of the inventions where possible, will be lost if major or all rights are inflexibly acquired by the Government in every case. Specifically, for example, and excluding situations where public interest in the nature or field of research conclusively demands retention of dominant rights by the Government as under subsections (1), (2), (3), and (4) of section 4(a) of S. 1809, it has been cogently suggested that in the absence of patent protection or substantial patent interest for the contractor.

(*a*) There will be minimal incentive to the contractor to identify and record patentable developments, so that the significance of such developments will be lost to the public.

(*b*) There will be little or no incentive for any one to commercialize products (in areas of general rather than Governmental use) since after the development of the products under the Government contract, no one would have any protection (against competition by others) in his investment for such commercialization.

(*c*) The small business contractor may find that the results of his research and development under the contract are free to be exploited by his larged competitor, to the detriment of the growth of small business.

(*d*) The contractor will be discouraged from making further developments with respect to subject matter which has in effect become dedicated to free availability to every one.

(*e*) Research and development contracts will be refused by many qualified contractors, especially those having the most valuable background of experience and ability, because of reluctance to risk their existing proprietary rights and to lose, in nongovernmental areas, the fruits of their long experience.

The position of the committee in support of S. 1809 accords with the position the committee has taken in past years relative to similar proposed legislation, i.e., relative to situations where demands of the national security or the general welfare warrant the Government's acquisition of greater rights in contract inventions and relative to the desirability of permitting a contractor to receive the greater rights in essentially all other cases. It may be noted, in passing, that as early as June 1961, the committee recorded its opposition to an earlier proposal for a Federal Inventions Administration, being of the opinion that such Administration would serve no useful purpose and that each Government agency can best administer its own patent affairs. It is noted that S. 1809 does not propose any such new Inventions Administration.

Turning to our reservation about the final provision of section 4(a) of S. 1809, i.e., the sentence now appearing in lines 18 to 22 of page 7 of the printed bill, it is strongly urged that some clarification is needed. Very apparently, the principal situation of "exceptional circumstances" would be one where the equities greatly favor the contractor, as when such contractor has an unusual amount of special knowledge and experience and a great deal of valuable know-how, either in research or commercial operation, in areas critically significant to the field in which the further research is desired. Under such circumstances, where the monetary consideration of the contract cannot possibly cover the very large value of the contractor's position, i.e., the value which will be of extraordinary advantage for the sake of the contracted research, it would seem plain that exceptional circumstances are present, including equitable considerations which predominantly favor the acquisition by the contractor of greater rights than a mere license. The public interest, in such case, may well be advanced by obtaining the services of this contractor (as most likely to be productive of desired results) through the inducement of the prospective acquisition of greater patent rights.

It is felt, however, that the present wording of this concluding provision of section 4(a) may well foreclose its applicability under these circumstances. Specifically, a Government agency might very likely adopt a theoretically warranted conclusion that the "public interest" is only "best served" by retaining title to all patents in the Government as the supposed representative of the public, there being nothing in the present language of the bill to indicate that strong equitable considerations in favor of the contractor might suffice to outweigh the presumably "best" position of the public in being granted full rights. Indeed, there is nothing in 4(a) that indicates any recognition of such equitable considerations, whereas the express recital of some limited situations involving such factors in section 4(b), could be construed as excluding any such considerations from the scope of the "exceptional circumstances" provision in 4(a). It is noted, in that connection, that this last provision is the only exception to the other parts of section 4(a); the benefits of section 4(b) are apparently not applicable to any situation coming within the numbered subsections of section 4(a).

We believe that the danger of this restrictive interpretation of the final proviso in section 4(a) is very real, and that it will result in serious disadvantage to the Government; i.e., inability to obtain the services of the best qualified and most productive contractors for research, especially in areas contemplated by section 4(a) (1) and (2), since those contractors will feel little inducement to sacrifice their hard-earned knowledge and experience.

By way of positive recommendation, it is suggested that the final sentence of section 4(a) (p. 7, lines 18 to 22 of the printed bill) be amended to read as follows (the amendment being by insertion of the wording marked for emphasis):

In exceptional circumstances, *which may include any equitable considerations that predominantly favor the contractor,* the contractor may acquire at the time of contracting or upon disclosure of the invention, greater rights than the nonexclusive license specified in section 3(b) (3) if the agency head certifies that such action will *advance or* best serve the public interest.

It is believed that amendment along these lines is desirable and necessary to clarify what we assume is the basic intent of the proviso; namely, to permit an exception where equitable considerations strongly favor the contractor. With the added wording, it will be plain that equitable considerations are to be taken into account, here as well as in the limited area of section 4(b). At the same time, the contracting agency can feel authorized to grant the exception if such action will truly advance the public interest; for example, as under the circumstances explained above, while there will be no compulsion on the agency to adopt a theoretical interpretation that the retention of essentially full title to patents is practically the only action that can be defined as "best" serving the public interest.

In conclusion, our committee appreciates this opportunity of expressing its support of the bill, on behalf of the Association of the Bar of the City of New York, and at the same time strongly recommends clarification of the above-noted provisions in section 4(a); e.g., as by amendment along the suggested lines, for the sake of basic workability of the general Government patent program, and, indeed, for the real interest of the public in getting the highest productivity and best results for its research dollars.

Respectfully submitted.

ROBERT S. DUNHAM,
Chairman, Committee on Patents.

THE NEW YORK PATENT LAW ASSOCIATION,
New York, N.Y., July 6, 1965.

Re bills to establish a national patent policy.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: This letter is submitted in lieu of an appearance and testimony on behalf of the New York Patent Law Association. Our association is very active and includes in its membership a majority of the lawyers in New York City, western Connecticut, and northern New Jersey who specialize in patent and trademark matters. A committee of our association has, for a number of years, been assigned the sole task of reviewing proposed legislation and other writings relating to Government patent policy and guiding our association's position with respect to this matter.

We first want to thank this subcommittee for holding hearings and accepting statements on the pending bills on Government patent policy. Our association strongly endorses the statement, made at the time S. 1809 was introduced, that: "it is clearly the intent of Congress that the basic guidelines of Government patent policy should be determined by the Congress" and "that the preferred method of accomplishing this objective is by the enactment of a comprehensive bill rather than by individual amendment to every bill authorizing Government research programs."

We have studied the bills now before this subcommittee designed to establish a uniform national policy concerning property rights in inventions made through the expenditure of public funds. We favor the passage of S. 1809 and recommend that it be enacted as soon as possible for the following reasons:

1. S. 1809 proposes a policy which recognizes the contributions of each of the parties.

2. S. 1809 offers the best opportunity for the development of an effective and equitable Government patent policy.

3. S. 1809 will prevent further deterioration of the patent system by piecemeal amendments to legislation authorizing research and development.

4. S. 1809 will provide a basis for incentives necessary to assure that technical advances resulting from Federal programs are utilized in non-Government areas with consequent benefits to the public at large.

We oppose enactment of S. 1899 because it provides for an inflexible Government title-to-all-inventions policy; it fails to recognize the equities of the contractors; and it can only serve to stifle the incentive of the contractors on which the Government must depend. We accordingly urge this subcommittee to report legislation which will provide the flexibility necessary to varying Government missions and the objectives sought by their research. Such legislation must, at

the same time, recognize the equities of contractors and recipients of Federal grants.

We are prepared to expand our statements in support of our endorsement of S. 1809 and our opposition to S. 1899. We have not submitted a more detailed review at this time because we have followed the statements submitted to date in support of S. 1809 and believe they set forth adequate and compelling reasons for the passage of S. 1809 rather than the inflexible and one-sided S. 1899.

We have drafted a limited number of minor amendments to S. 1809 which we believe would clarify the language, strengthen the position of our Government and our industries vis-a-vis foreign governments and industries, and increase the prospect of utilization of the inventions in nongovernmental fields.

Rather than extend this letter unduly, we will be pleased to present these suggested amendments at the request of the chairman or any member of this subcommittee to each of whom I am sending a copy of this letter.

Respectfully submitted.

JOHN N. COOPER, *President.*

NORTH AMERICAN AVIATION, INC.,
El Segundo, Calif., May 28, 1965.

Hon. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Senate Committee on the Judiciary, U.S. Senate, Washington, D.C.

MY DEAR SENATOR MCCLELLAN: We wish to submit the present statement in connection with the hearings presently being conducted by the Subcommittee on Patents, Trademarks, and Copyrights on proposed legislation concerning the disposition of inventions arising under Government contracts. The committee is to be commended for its thorough study of the complex patent rights problem, for the many hearings, studies, and reviews it has made over the past few years which have culminated in S. 1809 in the present Congress.

We are particularly pleased that the committee is attempting to formulate a uniform and equitable policy for all Government agencies, flexible in practice, which recognizes the need to stimulate the development and utilization of inventions by industry while recognizing and protecting the paramount public interest in technological growth. We recognize that the present diversity of legislation and policies reflects the different histories and statutory obligations of the various Government agencies but the resulting thicket now causes confusion, delays, and uncertainties to the Government, and to its contractors and vendors at all tiers. At present a contractor is faced with different patent requirements depending upon which agency he is dealing with even though the subject matter may be the same. The need for comprehensive legislation and the avoidance of further fragmentation is therefore apparent and urgent.

In developing advanced new defense and space systems of high technological content for the Government our company relies principally upon our strong technical capability in meeting specific contractual obligations and to generate the knowledge required to undertake new assignments. While our ability to acquire the skills to continue to meet increasingly complex technical problems in many disciplines is our principal asset in competing in the Government market, we nonetheless feel that patent factors can play an important role in bringing the results of work of companies like ours to other fields. Moreover, as a large prime contractor, our own performance is dependent upon that of a great number of subcontractors and vendors. It is the experience of DOD and NASA, as well as our own, that a patent policy which causes a vendor or subcontractor to fear loss of his proprietary position is a severe impediment to efficient administration and performance of program responsibilities. The protection of the proprietary position and commercial status of such smaller contractors is required not only for reasons of fairness, but also for efficient procurement. For these reasons we have a continuing interest in legislation on this subject.

We should like to express our strong support of the principles embodied in S. 1809. We believe they represent a sound balancing of the interrelated national interests which must be considered in establishing the patent policies of the United States. We are suggesting, however, certain ways in which we believe particular provisions of the bill could be clarified and strengthened.

The attached memorandum prepared by my staff discusses these suggestions and amplifies the considerations which we think should be reflected in an effective statute.

We wish to assure you of our continued willingness to cooperate in this important effort of the committee.

Sincerely yours,

J. L. ATWOOD, *President.*

MEMORANDUM

This memorandum amplifies the comments contained in the accompanying letter.

An important problem in the disposition of patent rights under Government contracts is to provide an effective means of transferring the inventions from the Government area to the often entirely different civilian environment. The task is to provide the necessary incentives to inventors and corporations to bring new products into the stream of commerce and benefit the people, while preventing unnecessary restrictions. Unless this is done the public will not obtain the full return from the current vast Government expenditures in R. & D. The experience over a number of years has been that such translation is frequently difficult, expensive, and unsure. Products of extreme technical complexity and sophistication developed for specific mission requirements often have no other use, and indeed their development is initially undertaken because of the absence of their commercial availability.

The utilization of developments originating under Government contracts thus poses more difficult problems than have been generally appreciated. It is considered that such utilization can be best accomplished with the traditional incentives offered by the patent system in the framework of our private ownership system. However, where a contractor is unable or unwilling to bring a patented product to the commercial market after a reasonable time it is just that the rights be then made available to others since the premise upon which the rights were granted has not been fulfilled and the public has not received full benefit.

There are still other areas where the most effective utilization of technical developments arising from Government programs can be best made by industry. It is understood to be national policy to foster the exportation of defense information to friendly countries in the interests of our national defense and foreign policy objectives, and also to obtain a return on defense investments from foreign countries. Some agreements in this area call for continuing cooperation between companies involving technical assistance, consultation, training of personnel, and exchange of technical data. Such programs involving the transfer and utilization of highly sophisticated technology can only be effectively conducted in the context of a private association of companies. While in many of these agreements involving the broad exchange of complex military technologies, the technical data and its knowledgeable utilization are of principal importance, patents are often valuable elements in the negotiation of a successful relationship. In other cases, which involve licenses of lesser scope directed to specific products whose design could be readily copied, foreign patents assume greater importance as the essential element of the agreement. All such activities are in furtherance of our national objectives, and their continuance should be uniformly sanctioned and encouraged under any new patent legislation.

Our study of S. 1809 indicates that most of the policy considerations discussed above and in Mr. Atwood's letter have been met. By permitting the Government contractor to retain patent rights in large areas, particularly those looking to the commercial markets, the results of Government research activity will be made available more readily to the entire economy through incorporation in commercial products. At the same time the bill recognizes and protects the predominant public interest in new technology, in providing means for insuring that the technology is in fact applied for public purposes, and to prevent the imposition of unreasonable restrictions on the use of technology. In areas of particular public concern or exclusive public sponsorship of technology, patent rights may be retained by the Government. Where the contractor retains patent rights, the contractor may be required to grant licenses to others when he has not in fact placed the invention in the stream of commerce.

Our suggestions for clarifying and improving the bill include the following: in section 4(a), provision for greater use of advanced waiver power, guidance on the application of the criteria, and administrative and judicial review of agency determinations applying this section; in section 4(b), modification of the requirement that a contractor must have an established nongovernmental commercial position in order to retain principal rights; and section 8, provision for the royalty-free licensing to all U.S. nationals of those patents in which the United States will retain title under this bill.

Section 4(a) delineates four criteria under which the United States shall acquire the principal rights in any invention made under a contract. These criteria are broadly stated and in order to insure their application in a uniform manner guidance should be given as to their application. In particular, the categories now require the disposition of rights at the time of contracting based upon the purpose and the technology of the contract. The nature of inventions actually made under the contract is not a factor. However, such inventions may relate only incidentally to the broad purpose or technology of the contract. For example, in an advanced space program, inventions are frequently made on such things as valves, fasteners, and welding techniques in which a contractor has an existing patent or industrial position. Therefore, provision should be made so that the Government would not be required to acquire exclusive rights in those inventions which are not of a dominant public interest under section 4(a) criteria.

In addition, liberalization of the provisions in section 4(a) to provide for advance waiver of Government rights in inventions at the time of contracting is recommended. This would considerably ease negotiation and administration of Government contracts. In subcontracting, for example, we find that a subcontractor wishes to establish his rights at the time of contracting to avoid uncertainties and time-consuming procedures for obtaining waivers on each invention. The prompt filing of patent applications would also be encouraged, and under this proposal the Government would suffer no loss, since the various safeguards of the bill would still be retained.

While review of agency determinations is desirably provided for in most cases, review is apparently not contemplated for agency action under section 4(a). This apparent absence is unnecessarily severe, would deny the customary review of procurement agency officers' decisions, and would not promote uniform practices. Finally, section 4(a) is more restrictive than the corresponding one in S. 1290, and while it is similar to a section in the President's memorandum of October 10, 1963, it does not have the flexibility of that section. Section 1(a) of the President's memorandum, after listing the categories where the Government would normally acquire exclusive rights (virtually identical with subparagraphs 1–4 of sec. 4(a)), goes on to provide that greater rights may be acquired by the contractor after the invention has been identified, where the invention is not a primary object of the contract, and the acquisition of greater rights is a necessary incentive to further investment and development.

Section 4(b) provides that in contracts calling for work in a field of technology in which the contractor has an existing technical position and competence he may ordinarily retain exclusive rights. However, a requirement for testing the contractor's technical competence in such field is that he have "an established nongovernmental commercial position." There are strong policy considerations for modifying this requirement by referring instead to a contractor's industrial or patent position. The principal consideration is that it would help the growth of new and often small companies and also the diversification of those companies which are now largely reliant on Government contracts. It would also foster the wider distribution and utilization of Government-developed technology.

A further suggested revision is directed to the utilization of patents acquired by the United States. The text of section 8(b) would sanction the licensing of patents for royalties by the United States and section 8(a) the bringing of suits for patent infringement against citizens of the United States by the Attorney General. It is believed that such activity by the Government would be ineffective in practice and would be the source of unnecessary controversies and litigation. It would clearly be inequitable to deprive the inventor-contractor of an invention on the basis that it falls within one of the categories of section 4(a) and that he has insufficient equities to retain an interest therein, and then grant the rights to another person with even less equity.

Moreover, the agency in granting exclusive licenses in Government-owned patents would be undertaking to direct the course of private technology and predict the course of competitive trends. Few of the agencies have had the requisite experience necessary to analyze the course of future development in civilian areas of technology and in general are not equipped to make determinations where competitive market forces are primary factors. If the contractor keeps title and is required to license others upon his own failure to exploit the invention, as is provided for in the bill, the public is spared the cost of paying for the Government administration of a licensing program, and further the contractor, who is most likely to exploit the invention, will be given the first opportunity to do so. It is recommended, therefore, that all inventions owned by the United States should be freely available to all U.S. citizens and corporations.

While the foregoing are the principal revisions suggested, there are other changes of a more technical nature which will not be specifically commented upon. If the committee wishes we would be pleased to furnish the text of language which would accomplish the changes suggested above as well as other more detailed changes.

THE UNIVERSITY OF TENNESSEE,
DEPARTMENT OF PHARMACOLOGY,
Memphis, Tenn., August 30, 1965.

HON. JOHN D. MCCLELLAN,
Committee on Patents,
U.S. Senate,
Washington, D.C.

DEAR SENATOR MCCLELLAN: First permit me to express my appreciation for initiating arrangements whereby my request to appear before the committee might be honored. I do wish to take this opportunity to express my regret that it was necessary for me to withdraw my request to appear on Tuesday, August 17. However, the pharmacology meetings in Philadelphia required me to be there on that day. Therefore, I will attempt to present to you in writing my views pertaining to bill S. 1809, which currently is being considered.

This bill, I am certain, represents a great deal of thought and effort and I consider it to be far superior to others such as 1899, submitted by Senator Russel Long.

First, possibly, I should introduce myself. I am professor and chairman of the Department of Pharmacology at the University of Tennessee Medical Units, Memphis, Tenn., a position which I have held since 1947. Previously, I held a similar chair at the University of Georgia College of Medicine, Augusta, Ga. I am a member of a number of scientific societies, including the American Society for Pharmacology & Experimental Therapeutics, American Society of Physiologists, American Heart Association, Sigma Xi, and Schwizerischen Vereins der Physiologen and Pharmakologen. I have conducted an active program in research in many fields and have published widely in several fields. I have no direct connections or positions with any pharmaceutical firm. At times, I have served as consultant for NIH and U.S. Food and Drug Administration.

As a citizen, I recognize that definite clarification is proper and necessary to protect the Federal Government and to establish reasonable policy and laws which will permit and encourage industry, the Government and the scientists to work together to develop knowledge which will provide all of us with better health and better medicine.

As I read the bill, I was disturbed by sections 3 and 4. Section 4(a)(2) states that the exclusive rights shall be acquired by the agency head in behalf of the United States at the time of entering into the contract when (p. 7, line 4) "the purpose of the contract is for exploration into fields which directly concern the public health, welfare, or safety." Practically all work dealing in the area of medical sciences could be considered directly concerned with the public health, welfare, or safety. This means that the agency head, in order to protect himself, must acquire at the time of entering into a contract, principal or exclusive rights to the inventions made by the contractor. True, this broad interpretation may not be given to section 4(a)(2) and, yet, agency heads in the Government must be conservative concerning such decisions. My experience has been that agency heads protect themselves and they can be expected

to acquire these exclusive rights very widely, if not in all cases involving areas of research related to medicine.

My experience and participation in research extends over a period of approximately 40 years. In the early days, my support was entirely from the university and from industry. As the economy of the Nation grew, and possibly as my contributions increased, I received appreciable governmental as well as industrial support.

Any bill which is passed by the Congress should not interfere or prevent scientists from getting support from many sources. It would be a most serious mistake to force the scientists of this country to depend entirely on the Government or entirely on industry and research foundations for their support. As scientists, we need the access to the new drugs and new chemicals which industry manufacturers, since they are frequently our tools whereby we learn more about disease processes. As I read this bill and think back over my experiences, it appears to me that this bill will tend to force many scientists to either accept Government money, or industrial money, but not both. Inventions are frequently the result of slowly developing ideas which mature into definite inventions. It is often impossible to be certain of the portion of the invention conceived while working under an agency or while working under contract on a project financed by a pharmaceutical firm, or while working on university supported programs. The most profitable and worthwhile research is frequently accomplished when the scientist and his associates are investigating a disease process with Government and industrial laboratory support and when they are using tools in the form of drugs or new chemicals to determine their effect on this disease process. These new chemicals are often the key to providing new information on the pathology and physiology of the disease. Under the regulations, as presented in bill S. 1809, it seems to me that scientists will be forced into the awkward situation where they will have accepted, in a sincere manner, financial support from the Government and from an industrial firm, and then find themselves confronted with a situation that they have made a discovery in performing studies supported by the Government, industry, and the university. It is more or less like whether breakfast, lunch, or dinner was the meal which made a boy grow into a man. It is my feeling that the university has definite rights and responsibilities and these should not be denied to them by a blanket clause requiring all discoveries to become exclusive property of the Government. Many universities have benefited from a wise policy pertaining to discoveries—the Wisconsin foundation is an excellent example.

It is my sincere hope that the bill can be so formulated that it will not remove the stimulus of granting financial rewards to productive efforts and will not interefer with cooperative programs involving support from funds from several sources. I know that you recognize the contributions that American industry and private enterprise have made to the improvement of medicine under the system which has been operating. The private enterprise system must be preserved while we are protecting the Government investment. I feel that the bill, as written, will hamper the development of new drugs unless a means is found to provide more freedom for the scientist to utilize new chemicals and new drugs, as well as receive financial support from the Government.

Most sincerely yours,

ROBERT A. WOODBURY, M.D., Ph. D.,
Professor and Chairman.

PATENTS, TRADE-MARK, & COPYRIGHT SECTION,
STATE BAR OF TEXAS,
July 6, 1965.

Senator JOHN L. MCCLELLAN,
U.S. Senate,
Washington, D.C.

SIR: In my capacity as chairman of the Patent, Trade-mark, & Copyright Section of the State Bar of Texas, I am herewith transmitting to you for consideration by you and your Subcommittee on Patents, Trademarks, & Copyrights of the Committee on the Judiciary six copies of two resolutions passed by the Patent, Trade-mark, & Copyright Section of the State Bar of Texas at its last annual meeting on July 2, 1965. One of these resolutions sets forth the views

of the section relative to bill S. 1899 introduced into the 89th Congress by Senator Long and the other resolution sets forth the views of the section relative to bill S. 789 introduced by Senator Saltonstall and bill S. 1809 introduced by you.

The section hopes that your subcommittee, and ultimately the Congress, will adopt the views expressed in these resolutions.

Very truly yours,

MELVIN F. FINCKE, *Chairman.*

RESOLUTION

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas believes that progress, advancement, and the public good are best served by private enterprise rather than by Government intervention or ownership; and

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas believes that the patent system has demonstrated over the past many decades that it affords a vital and effective incentive to private enterprise to assume the economic risks involved in developing new products, in introducing them to the public, and then promoting their use; and

Whereas the Patent, Trade-mark, & Copyright Section of the State Bar of Texas is convinced that the Government cannot and should not assume a monopolistic postion with respect to the exclusive rights afforded by the patent grant and cannot and should not undertake the introduction and exploitation of new products in the public marketplace in competition with private enterprise: and

Whereas bill S. 1899 has been introduced into the Senate of the United States and has the purpose of (*a*) requiring the United States to take exclusive rights and title to any invention made in the course of or in consequence of any scientific or technological research development or exploration activity and resulting directing or indirectly from any contract or lease entered into or any grant made by, or on behalf of, any governmental department agency; and (*b*) establishing in the executive branch of the Government a Federal Inventions Administration: Now, therefore, be it

Resolved, That, the Patent, Trademark, and Copyright Section of the State Bar of Texas (*a*) opposes the extreme and inequitable approach of bill S. 1899 introduced into the 89th Congress toward inventions resulting from Government contracts; and (*b*) opposes the establishment of a Federal Inventions Administration as needless, costly, and against the best interests of this country and the principles upon which it was founded.

HOPE COLLEGE,
Holland, Mich., July 27, 1965.

HON. JOHN MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: In your concern with the bills S. 789 (Saltonstall), S. 1899 (Long), and S. 1809 (McClellan), I think your bill, S. 1809, is so far the best compromise between Government and private industry and the extent of control each should have on patent rights. American industry, with its inventiveness, research, and production, has found competition not only the spark for new ideas but a necessary weapon for fighting the evil of profiteering. Bill S. 1899 seems to restrict research and industry in a way by placing patent rights in the hands of the Government whenever any Government money is used in any way in the research or production of a thing.

This seems an unnecessary kind of restriction since all private property is subject to the right of eminent domain in the Government, and may be taken, in payment of fair compensation, whenever a genuine public need is demonstrated.

Scientific industry and technology must make profits to help guarantee further research and to pay the often high cost of manufacturing. It is a moot question whether the public is more greatly benefited financially by paying the margin of profit over the counter or by paying possibly larger amounts through taxes. Federal research expenditure for 1958 was over $2½ billion. It would be interesting to know comparatively the number of new discoveries from research resulting from Government-sponsored research as contrasted with that of private research. Private pharmaceutical industry, for instance, has developed and discovered most

of our new lifesaving drugs. We must protect this kind of research to the best of our ability with a patent law that fires rather than deadens incentive. Your bill protects industry in its rights as does S. 789 to some extent, but S. 1899 would be duplicating at the taxpayer's expense such research activity that could and should be carried on by industry and other private agencies.

I should like these remarks made a part of your hearings record; i.e., that of Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary.

Sincerely,

C. A. VANDERWERF,
President of Hope College, Professor of Chemistry.

WESTERN ELECTRONIC MANUFACTURERS ASSOCIATION,
Palo Alto, Calif., July 30, 1965.

Hon. JOHN MCCLELLAN,
Chairman, Senate Judiciary Subcommittee on Patents, Trademarks, and Copyrights, U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: I am taking this opportunity to write to you to express the viewpoint of the Western Electronic Manufacturers Association regarding the proposed legislation on patents pending before your subcommittee.

The Western Electronic Manufacturers Association is a trade association of companies engaged in electronic manufacturing or electronic research and development in the 13 Western States. Our total membership today is 360 companies. These range in size from small companies to large corporations.

Some of our member companies employ many thousands of persons and have been important prime contractors in the Government's defense program. However, the majority are smaller firms which have served as subcontractors or component suppliers. These companies are technologically based and dependent upon their individual inventiveness and improvements in the state of the art to maintain a position in this competitive market. Accordingly, our association has a vital interest in the subject matter of the vesting of patent rights developed under research and development contracts with the Federal Government.

For some time we have been opposed to Senator Long's unequivocal position that the Government should be entitled to exclusive patent ownership. His pending bill S. 1899 ignores the fact that if American industry is to apply its accumulated technology and know-how in the solution of developmental problems, it must be afforded patent protection to maintain viability and be of even further service to the Government. Moreover, the incentive of attaining a proprietary position must be offered to stimulate the growth of small business.

Senator Saltonstall's bill S. 789 presents a much sounder understanding of the respective needs of Government and private industry, and equitable patent legislation could be built on the fundamental points set forth.

We heartily endorse S. 1809, which you introduced, because it is a well-developed bill which recognizes the equities of the joint effort by industry and the Government under research and development contracts. As in the statement of patent policy issued by the President, this bill analyzes the several situations which can exist and establishes equitable criteria for distribution of any resulting patent rights.

However, we suggest that the bill be strengthened to establish definitive rights at the time of contracting to give a potential contractor greater assurance of protection in the area of self-developed technology. Perhaps some of the language of S. 789 might be helpful in this regard.

We also feel that the bill should be expanded to insure the protection of inventions from foreign exploitation.

Thank you for the opportunity to present this statement in behalf of the Western Electronic Manufacturers Association.

Sincerely,

W. H. HEFLIN, *President.*

WESTINGHOUSE ELECTRIC CORP.,
PATENT DEPARTMENT,
Pittsburgh, Pa., May 14, 1965.

S. 1809 (McClellan).

Hon. JOHN L. MCCLELLAN,
U.S. Senate,
Washington, D.C.

DEAR MR. MCCLELLAN: We have studied carefully S. 1809 dealing with the disposition of rights to inventions made under Government R. & D. contract.

We believe that the obectives sought are sound and that the approach taken is such, generally speaking, that substantial benefit should result to the general economy, the Government, and contractors if the subject bill should be enacted into law and administered reasonably.

It would only be natural, I suppose, that we would prefer some changes in specific language. We, therefore, take the liberty of suggesting some major points where we think confusion may arise or problems may develop in administering the bill if it should be enacted as introduced.

Referring to section 3(b)(5), the determination of reasonable terms and conditions, and, perhaps, the granting of compulsory licenses is placed in the hands of the agency involved. It would seem to us that it might be advantageous from the Government standpoint as well as from the public benefit that the agency head do no more than "supervise" the granting of such licenses. In this manner, the burden would be transferred from the agency head to the contractor in an area where we believe the contractor would be more than happy to assume the burden. It is suggested that lines 3 to 11 be revised as indicated in the following wherein insertions are underlined and deletions are lined out:

"terms and conditions *subject to review by* ~~as~~ the agency *head* ~~may prescribe~~ upon a determination made by such agency head, after affording the opportunity of a hearing to the owner of those rights, that (a) the owner of those rights has not exerted substantial efforts to bring the invention to the point of practical application and (b) the public interest would be *better* served by *requiring the owner to license one or more* ~~the issuance to~~ other persons ~~of licenses for the~~ *to* practice ~~of~~ that invention;"

Referring to section 3(b)(8), we note that there is no excuse whatsoever permitted for failing promptly and fully to report an invention. In view of the serious penalty; i.e., forfeiture, involved and because reasonable men can well differ on reasonable time for reporting as well as whether reporting is required, we would urge that, in line 12 on page 6, there be inserted after the word "knowingly" the words "and in bad faith". In support of the above suggestion, it is noted that conceptions and first actual reductions to practice form the basis for reporting of inventions. As a quick glance through board of interference and court decisions on interference situations will disclose, it is often not easy to determine when a conception has been made and when an actual reduction to practice has been made. Many interferences and court cases hinge on these determinations and, since there is usually involved a question of judgment with respect to which attorneys will differ, it is believed that a sort of "rule of reason" should be applied in this area and that severe penalties should not be enforced unless an element of fraud is present.

Referring to section 4(a), the proposed bill provides that the "agency head shall acquire" certain rights. It may be that the rights involved are not worth acquiring and it may be useful from the standpoint of economics, if for no other reason, that title be avoided and the necessity of, or at least a decision concerning, the filing of patent applications be avoided. You might like to consider inserting in line 20 on page 6 after the word "shall" the words "reserve the right to".

Referring to section 4(a), and more particularly to the criteria identified as justifying the taking of principal rights, there are certain ambiguities or at least certain degrees of indefiniteness which, in our opinion, are likely to cause future problems.

Referring to subparagraph (1), it would seem to us of doubtful value for the Government to acquire title to all inventions made merely because the invention

may be required for use by governmental regulations. In this connection, we would distinguish, for example, between a contract having as an object an improvement or cost reduction or some other minor modification of a well-known drug such as "aspirin" as distinguished from research directed to a significantly important medical advance such as a cancer cure. The same approach is applicable to subparagraph (2) where you might distinguish between an improvement in stair treads to minimize the danger of slipping as compared with a device for absolutely preventing collisions between vehicles. To soften the impact on contractors without disadvantaging the public, both of these criteria might be restricted to improvements or inventions of critical significance in connection with the end objective.

Thus, referring to section 4(a)(1), we suggest inserting in line 3, page 7 after the word "regulations" the words "provided that such products, processes, or methods are of critical significance and that no reasonably competitive item is readily available."

In line 5, page 7 (sec. 4(a)(2)), we urge insertion following "concern" the words "and are of critical significance in connection with."

Further, with respect to section 4(a)(2), the word "welfare" is so general as to be indefinite; we recommend deletion of that word.

Referring to subparagraph (3) under section 4(a), there will certainly be some difficulty in determining whether the Government is the principal or prime developer of a field. For this reason, we would urge consideration of limiting the application of this subparagraph to those situations wherein the Government has been "substantially the sole" developer.

Again, in this same subparagraph, the Government may acquire greater rights whenever the invention "might" confer on the contractor a "preferred or dominant position." It can be argued and has been argued under the present DOD regulations that every patent confers a preferred position. Indeed, this is the purpose of the grant of a patent. It is not this sort of preferred position which you have in mind, I am sure, and, similarly, others who have proposed this type of language have not had this kind of dominance in mind. Therefore, it is believed that it would be helpful to reword this criterion as follows:

"rights at the time of contracting is likely to confer on the contractor a dominant position;".

Referring to section 7, we note the possibility that the agency head may direct the issuance of a patent to the Government in situations where the contractor has already filed a patent application. We would urge consideration of suitable reimbursement to the contractor in such a situation.

Referring to section 8, we would anticipate considerable protest or at least adverse comment concerning the requirement that agency heads shall affirmatively protect and preserve the property rights of the United States in patents owned by the United States. It could be argued that the property right carries the privilege of protection and preservation and, therefore, it would be better not to insist that the Government prosecute U.S. citizens for using patents issued for the benefit of the U.S. public at large.

With respect to section 8(b), it is noted that the agency head cannot in fact grant an exclusive license because the contractor is granted a reserved nonexclusive license and presumably the Government should retain a nonexclusive license for its own governmental operations. In this area, i.e., exclusive licensing, we would urge a careful study be made because, at first thought, it appears to be repugnant to argue that the public benefit requires the taking of exclusive rights from the contractor only to, in turn, pass on those exclusive rights to another citizen or U.S.-based firm. It is for this reason that many believe that any citizen who wishes to use a Government-held patent should be entitled to a free, nonexclusive license.

Referring to lines 10 and 11 on page 15, the license provided therein may be granted with or without the payment of royalty to the United States. Some of us fear that this type of language can lead to governmental regulation of industry by determining who can have a license and how much he may have to pay. It has been advocated, for example, that the Government grant exclusive licenses to a small company to help it grow larger and then when it is large enough to stand on its own feet, the license would be taken away and given to someone else or the royalty rate would be increased or some other step taken to

remove any advantage it might have. Many fear this type of Government entry into the control of the business of the Nation.

Referring to section 9, provision is made in subsection (b) that a report and summary of findings be made with respect to those inventions wherein the agency involved has acquired no greater rights than a royalty-free license. No such reporting is required when title is taken. In order to avoid the burden of making reports under license situations, contracting officers may well have a tendency to press for taking title wherever possible in order to avoid this reporting function. Moreover, for the reports to be of greatest value to Congress, it would seem that similar reports should be made with respect to situations where the Government has taken the principal rights. For example, such reports would be valuable in determining whether the various agencies are reasonably applying the various criteria. Therefore, we would suggest the insertion of a subsection reading as follows:

"The number and general nature of such inventions with respect to which the agency acquired greater rights than a royalty-free license in accordance with section 4 and a summary of the findings of fact upon which a determiantion of the applicability of sections 4(a) (1), (2), (3), or (4) was based."

We sincerely hope that the foregoing will be of some assistance to you.

Very truly yours,

T. L. BOWES,
General Patent Counsel.

LONDON, *July 3, 1955.*

Senator JOHN MCCLELLAN,
Senate Subcommittee on Patents,
Washington, D.C.:

I regret my inability to appear in person before your committee for I spent many months during my term as President Kennedy's science adviser exploring facets of Federal patent policy. Sound Government policy must be flexible enough to satisfy both private and public interest to provide maximum availability of invention and technology for defense, and maximum incentives for economic development as well. The patent policy memorandum of October 10, 1963, reflected a careful effort to balance these requirements. It was the product of coordinated study of the Government agencies which must enlist contractors to perform their functions and had the endorsement of those agencies.

McClellan bill S. 1809 would implement this balanced and equitable policy, if possible. I would appreciate having my 1963 testimony and responses to questions before Senator Long entered as testimony for your hearings.

J. B. WIESNER,
Dean, School of Science, MIT.

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