1963

Memorandum of October 10, 1963

[GOVERNMENT PATENT POLICY]

Memorandum for the Heads of Executive Departments and Agencies

Over the years, through Executive and Legislative actions, a variety of practices has developed within the Executive Branch affecting the disposition of rights to inventions made under contracts with outside organizations. It is not feasible to have complete uniformity of practice throughout the Government in view of the differing missions and statutory responsibilities of the several departments and agencies engaged in research and development. Nevertheless, there is need for greater consistency in agency practices in order to further the governmental and public interests in promoting the utilization of federally financed inventions and to avoid difficulties caused by different approaches by the agencies when dealing with the same class of organizations in comparable patent situations.

From the extensive and fruitful national discussions of government patent practices, significant common ground has come into view. First, a single presumption of ownership does not provide a satisfactory basis for government-wide policy on the allocation of rights to inventions. Another common ground of understanding is that the Government has a responsibility to foster the fullest exploitation of the inventions for the public benefit.

Attached for your guidance is a statement of government patent policy, which I have approved, identifying common objectives and criteria and setting forth the minimum rights that government agencies should acquire with regard to inventions made under their grants and contracts. This statement of policy seeks to protect the public interest by encouraging the Government to acquire the principal rights to inventions in situations where the nature of the work to be undertaken or the Government's past investment in the field of work favors full public access to resulting inventions. On the other hand, the policy recognizes that the public interest might also be served by according exclusive commercial rights to the contractor in situations where the contractor has an established non-governmental commercial position and where there is greater likelihood that the invention the policy recognizes that its civilian use than would be the case if according exclusive commercial rights to the contractor in situations where the contractor has an established non-governmental commercial position and where there is greater likelihood that the invention would be worked and put into civilian use than would be the case if the invention were made more freely available.

Wherever the contractor retains more than a non-exclusive license, the policy would guard against failure to practice the invention by requiring that the contractor take effective steps within three years after the patent issues to bring the invention to the point of practical application or to make it available for licensing on reasonable terms. The Government would also have the right to insist on the granting of a license to others to the extent that the invention is required for public use by governmental regulations or to fulfill a health need, irrespective of the purpose of the contract.

The attached statement of policy will be reviewed after a reasonable period of trial in the light of the facts and experience accumulated. Accordingly, there should be continuing efforts to monitor, record, and evaluate the practices of the agencies pursuant to the policy guidelines.

This memorandum and the statement of policy shall be published in the FEDERAL REGISTER.

JOHN F. KENNEDY

STATEMENT OF GOVERNMENT PATENT POLICY

BASIC CONSIDERATIONS

A. The government expends large sums for the conduct of research and development which results in a considerable number of inventions and discoveries.

B. The inventions in scientific and technological fields resulting from work performed under government contracts constitute a valuable national resource.

C. The use and practice of these inventions and discoveries should stimulate inventors, meet the needs of the government, recognize the equities of the contractor, and serve the public interest.

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

E. The public interest is also served by sharing of benefits of government-financed research and development with foreign countries to a degree consistent with our international programs and with the objectives of U.S. foreign policy.

F. There is growing importance attaching to the acquisition of foreign patent rights in furtherance of the interests of U.S. industry and the government.

G. The prudent administration of government research and development calls for a government-wide policy on the disposition of inventions made under government contracts reflecting common principles and objectives, to the extent consistent with the missions of the respective agencies. The policy must recognize the need for flexibility to accommodate special situations.

POLICY

SECTION 1. The following basic policy is established for all government agencies with respect to inventions or discoveries made in the course of or under any contract of any government agency, subject to specific statutes governing the disposition of patent rights of certain government agencies.

(a) Where

(1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use)

(d) Where

(1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use) by the general public at home or abroad, or which will be required for such use by governmental regulations; or

(2) a principal purpose of the contract is for exploration into fields which directly concern the public health or public welfare; 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 the principal developer of the field, and the acquisition of exclusive rights at the time of contracting might confer on the contractor a preferred or dominant position; or

(4) the services of the contractor are

(i) for the operation of a government-owned research or production facility; or

(ii) for coordinating and directing the work of others,

the government shall normally acquire or reserve the right to acquire the principal or exclusive rights throughout the world in and to any inventions made in the course of or under the contract. In exceptional circumstances the contractor may acquire greater rights than a nonexclusive license at the time of contracting, where the head of the department or agency certifies that such action will best serve the public interest. 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 1(a) and is a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application.

(b) In other situations, 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 technology in which the contractor has acquired technical competence (demonstrated by factors such as know-how, experience, and patent position) directly related to an area in which the contractor has an established nongovernmental commercial position, the contractor shall normally acquire the principal or exclusive rights throughout the world in and to any resulting inventions, subject to the government acquiring at least an irrevocable non-exclusive royalty free license throughout the world for governmental purposes.

(c) Where the commercial interests of the contractor are not sufficiently established to be covered by the criteria specified in Section 1(b), above, the determination of rights shall be made by the agency after the invention has been identified, in a manner deemed most likely to serve the public interest as expressed in this policy statement, taking particularly into account the intentions of the contractor to bring the invention to the point of commercial application and the guidelines of Section 1(a) hereof, *provided* that the agency may prescribe by regulation special situations where the public interest in the availability of the inventions would best be served by permitting the contractor to acquire at the time of contracting greater rights than a non-exclusive license. In any case the government shall acquire at least a non-exclusive royalty free license throughout the world for governmental purposes.

(d) In the situation specified in Sections 1(b) and 1(c), when two or more potential contractors are judged to have presented proposals of equivalent merit, willingness to grant the government principal or exclusive rights in resulting inventions will be an additional factor in the evaluation of the proposals.

(e) Where the principal or exclusive (except as against the government) rights in an invention remain in the contractor, he should agree to provide written reports at reasonable intervals, when requested by the government, on the commercial use that is being made or is intended to be made of inventions made under government contracts.

(f) Where the principal or exclusive (except as against the government) rights in an invention remain in the contractor, unless the contractor, his licensee, or his assignee has taken effective steps within three years after a patent issues on the invention to bring the invention to the point of practical application or has made the invention available for licensing royalty free or on terms that are reasonable in the circumstances, or can show cause why he should retain the principal or exclusive rights for a further period of time, the government shall have the right to require the granting of a license to an applicant on a non-exclusive royalty free basis.

(g) Where the principal or exclusive (except as against the government) rights to an invention are acquired by the contractor, the government shall have the right to require the granting of a license to an applicant royalty free or on terms that are reasonable in the circumstances to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the contract.

(h) Where the government may acquire the principal rights and does not elect to secure a patent in a foreign country, the contractor may file and retain the principal or exclusive foreign rights subject to retention by the government of at least a royalty free license for governmental purposes and on behalf of any foreign government pursuant to any existing or future treaty or agreement with the United States.

SEC. 2. Government-owned patents shall be made available and the technological advances covered thereby brought into being in the shortest time possible through dedication or licensing and shall be listed in official government publications or otherwise.

SEC. 3. The Federal Council for Science and Technology in consultation with the Department of Justice shall prepare at least annually a report concerning the effectiveness of this policy, including recommendations for revision or modification as necessary in light of the practices and determinations of the agencies in the disposition of patent rights under their contracts. A patent advisory panel is to be established under the Federal Council for Science and Technology to

(a) develop by mutual consultation and coordination with the agencies common guidelines for the implementation of this policy, consistent with existing statutes, and to provide over-all guidance as to disposition of inventions and patents in which the government has any right or interest; and

(b) encourage the acquisition of data by government agencies on the disposition of patent rights to inventions resulting from federally-financed research and development and on the use and practice of such inventions, to serve as basis for policy review and development; and

(c) make recommendations for advancing the use and exploitation of government-owned domestic and foreign patents.

SEC. 4. *Definitions:* As used in this policy statement, the stated terms in singular and plural are defined as follows for the purposes hereof:

(a) Government agency—includes any Executive department, independent commission, board, office, agency, administration, authority, or other government establishment of the Executive Branch of the Government of the United States of America.

(b) "Invention" or "Invention or discovery"—includes any art, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(c) Contractor—means any individual, partnership, public or private corporation, association, institution, or other entity which is a party to the contract.

(d) Contract—means any actual or proposed contract, agreement,

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(d) Contract—means any actual or proposed contract, agreement, grant, or other arrangement, or sub-contract entered into with or for the benefit of the government where a purpose of the contract is the conduct of experimental, developmental, or research work.

(e) "Made"—when used in relation to any invention or discovery means the conception or first actual reduction to practice of such invention in the course of or under the contract.

(f) Governmental purpose—means the right of the Government of the United States (including any agency thereof, state, or domestic municipal government) to practice and have practiced (made or have made, used or have used, sold or have sold) throughout the world by or on behalf of the Government of the United States.

(g) "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 and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

[F.R. Doc. 63-10888; Filed, Oct. 11, 1963; 9:21 a.m.]

1965

Norman J. Latker *
and
Ronald J. Wylie †

UTILIZATION OF GOVERNMENT-OWNED HEALTH AND WELFARE INVENTIONS +

Government Involvement in Research and Development

It may well be, as stated by a former U. S. Attorney General, that the use and enjoyment of a large segment of our annual crop of inventions by the Government and by the people of the United States may depend upon the control of patent rights arising from Government-sponsored research.[1]

Over the years the Government has acquired all right, title and interest in and to a considerable number of inventions which have originated from the research and development activities of Government employees, grantees, and contractors. Today the Government appears to be, or is certain to become, the largest single owner of patents in the country. In June 1953 the Government owned outright a total of 4,061 inventions covered by unexpired patents, which were under the administrative control of the various governmental agencies. Two years later the total had increased to 5,203. It is estimated that by September 1960 the Government owned approximately 12,000 inventions covered by active patents. At the rate such inventions are being acquired, it is conservatively estimated that within the next six years the total number of patented inventions wholly owned by the Government will exceed 15,000 and may even approach 20,000. By that time, the number of new acquisitions will be offset by the number of patents expiring, and the portfolio will be substantially in balance.

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+ From an address given by Mr. Latker before the Washington Chapter of the Instrument Society of America. February 1, 1965.

* Patent Advisor, Office of the Director, National Institutes of Health.
† Contract Operations Officer, Division of Biologics Standards, National Institutes of Health.

1 *Rep. Atty. Gen.*, Investigations of Government Patent Practices and Policies, Vol. 1, 2 (1947).

Government Use of Patents

Some years ago a Science Advisory Board, formed at the request of the Secretary of the Department of Commerce and comprised of a representative group of our country's foremost leaders, issued a report to the Secretary wherein it was stated:

> The patent system of the United States was set up originally to benefit the public by advancing the useful arts. It does this by creating a temporary monopoly, *thereby rendering possible the hazardous development of untried inventions*, which would otherwise not come to fruition to add to the general well-being and increase the standard of living of the people. By its substantial rewards it stimulates invention, and the assiduous study and persistent effort on which invention is based. That it has been successful needs no demonstration for its results are all about us[2] (emphasis added).

We believe that the above statement represents the crux of the argument of those in Congress who champion a policy of leaving invention rights with Government contractors rather than with the Government. Thus, Representative Daddario of Connecticut recently stated,

> Without some form of protection, it is a business axiom that there is little incentive to develop an invention. It may be argued that if there is a demand for a product, business will invest, produce and market it. But in the complexities of modern business, this is *not* the case. Risk capital requires
there is little incentive to develop an invention. It may be argued that if there is a demand for a product, business will invest, produce and market it. But in the complexities of modern business, this is *not* the case. Risk capital requires some assurances of its own recovery and a fair margin of profit. The lengthy and costly procedure of developing and marketing a new item demands too much capital investment for it to be risked without some semblance of protection. Today, of every twenty-six new products offered to the public, only one survives as a successful venture. Many companies have gone broke bringing out products which either did not touch the public's fancy or appeared at the wrong time. In addition, new products remain new for a very short time. They are quickly succeeded by products of better design and lower price[3] (emphasis added).

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[2] 18 *Journal of Patent Office Society, Report of the Committee on the* Relation of the Patent System to the Stimulation of New Industries (1936), 94, 95.

[3] Daddario, Government Patent Policy Legislation, *American Bar Association Journal*, July 1961, p. 671.

When the Government retains title in inventions, does it capitalize in any way on the monopoly that has been granted to it? Based on past experience, the answer would have to be "no." The role of the Government in promoting technological advances it owns and in encouraging their exploitation has long been neglected. The Government has, traditionally, limited its efforts in the encouragement of exploitation to merely calling public attention to the existence of patents and inviting any interested person to exploit the disclosed invention without charge.

The Government generally offers a non-exclusive, royalty-free license under its patents to anyone, including foreigners. Historically, moreover, it has not brought suit against anyone for infringment, and thus many of its inventions, when they are put to use, are used by non-licensed manufacturers because they know they will not be sued by the Government-owner.

When a patent is not put to the use intended, as when it is held by the Government and the invention covered thereby is made available to all, the patent has but little greater value than any other printed disclosure of the invention[4] (emphasis added). It is not difficult to understand that the public benefits much more when it can receive the hardware described by the patent than it *invention*[4] (emphasis added). It is not difficult to understand that the public benefits much more when it can receive the hardware described by the patent than it does when it is merely given an opportunity to read about the invention.

Utilization

The primary purpose of the patent system of this country is to stimulate new industries and the expansion of existing ones. This has always been an important matter, but it becomes particularly important as the

[4] Watson, Management of Government-owned Inventions, *21 Federal Bar Journal*, Winter 1961, 121 at p. 123.

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[5] *Federal Regist*
1963, p. 10943.
[6] Gore, Toward
Rights Under Gc
1961, 105 at p. 11

country concerns itself with economic growth in an effort to create new job opportunities for an expanding labor force. Along this line there is growing evidence of interest within the Government in the more effective utilzation of Government owned patents. President Kennedy's October 10, 1963 statement on Government Patent Policy [5] focused on this issue by stating: ". . . the Government has a responsibility to foster the fullest exploitation of the inventions for the public benefit." More specifically, he stated that the public interest might best be served in particular situations by according exclusive rights to the inventions to those who might thus be induced to work the invention and put it into civilian use.

Of course, it is understood that not all Government-owned inventions are alike, and not all exploitation requires that the potential exploiter be assured of some exclusive rights. The degree of development necessary to bring the invention to the commercial market undoubtedly dictates the need for exclusivity. Where an agency is stressing applied research, perhaps little development is needed. An agency, such as the Department of Health, Education, and Welfare, in the great part oriented toward basic research may have potentially good inventions undeveloped because they are not directly related to the research goals... Adapting the new idea for commercial sale at competitive prices, tooling for production, and the creating and sampling of markets may be of no concern to the Government, but the activities are vital to commercial exploitation, and they require vast expenditures of capital and energy. Almost invariably, the cost of transforming a completed invention into a salable product greatly exceeds the cost of making the invention itself.[6] The prospect of having the article

oriented toward basic research may have potentially good inventions undeveloped because they are not directly related to the research goals. Adapting the new idea for commercial sale at competitive prices, tooling for production, and the creating and sampling of markets may be of no concern to the Government, but the activities are vital to commercial exploitation, and they require vast expenditures of capital and energy. Almost invariably, the cost of transforming a completed invention into a salable product greatly exceeds the cost of making the invention itself.[6] The prospect of having the article

[5] *Federal Register*, Statement on Government Patent Policy, October 10, 1963, p. 10943.

[6] Gore, Toward A Sound National Policy for Disposition of Patent Rights Under Government Contracts, *21 Federal Bar Journal*, Winter 1961, 105 at p. 115.

copied soon after being introduced into the market by others who have borne no such financial burden of development and therefore can sell at a lower price is not one calculated to encourage exploitation of many inventions. It is safe to say that industry would rather invest their capital exploiting their own inventions than develop an invention for which they will have no patent protection.

That industry requires some protection as an incentive to the further development of certain areas of technology may be illustrated by the fact that after the 1954 Atomic Energy Act removed many of the bars to patent protection which had been present under the 1946 Act, the interest of private enterprise in the proprietary development of all areas of nuclear technology substantially increased. Thus, even though the incentive is somewhat limited (because Congress was concerned lest "insiders" might secure a monopoly position), it is clear that the patent incentive has been an important factor in the development of nuclear technology.[7]

For inventions in which exclusivity appears essential to commercial exploitation, several approaches are available. Two of the most obvious are (1) to leave title to inventions in the employee, grantee, or contractor who generated them; (2) to place title in the Government and later permit sale of full title to some party thought best suited to develop the invention. But these approaches

inventions in the employee, grantee, or contractor who generated them; (2) to place title in the Government and later permit sale of full title to some party thought best suited to develop the invention. But these approaches are in conflict with the increasing tendency in Congress to require that title in inventions generated by research be vested in the Government for later dedication to the public. A less obvious approach, which will be discussed later in greater detail, is exclusive licensing which would permit reconciliation of the need to grant some exclusivity with the need to retain control of title by the Government.

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[7] Hamman, An Appraisal of the Atomic Energy Field After 20 Years of the Patent Title Policy, *The Patent, Trademark, and Copyright Journal of Research and Education*, Vol. 6, Fall 1962, 377 at p. 407.

The President's Memorandum

The introductory section of the Presidential Memorandum of October 10, 1963, speaks to, as noted above, the Government's responsibility to fully exploit its inventions and the way in which the public interest might best be served by according exclusive rights to those who might be induced to work them. When going from the general to the specific, i.e., when one attempts to apply this policy to health and welfare inventions, these thoughts seem to lose much of their impact. The implementing section or policy section, as it is referred to in the memorandum, sets forth, in essence, the rules under which an Agency or Department should leave title to an invention financed with Government funds to the generating contractor as against taking title to the invention by the Government.

Section 1(a) of the memorandum sets forth four categories of research and development contracts under which the contracting agency is directed to acquire, or reserve the right to acquire, title in and to any inventions made in the course of or under such contracts. One of the four categories of contracts outlined in Section 1(a) deals with contracts for exploitation into fields which directly concern the public health or public welfare. It is clear that all contracts or grants entered into by the Department of Health, Education, and Welfare can be construed as falling within this category. Section 1(a) continues by providing an exception to its general rule of obtaining title for the Government. This exception states that the contractor may obtain title after the invention has been identified, where the invention is *not* a primary object of the contract, provided the acquisition of title is a necessary incentive to call forth private risk capital to bring the invention to the point of practical application.

A careful look at DHEW inventions shows that nearly all would have to be considered the primary purpose of the contract or grant under which they are generated.

Under these circumstances, Section 1(a) offers no means of providing exclusivity, when additional development of the invention is shown to be necessary.

Section 1(b) of the memorandum defines a category of contracts under which title to inventions generated therefrom may be left to the generating contractor or grantee. This section indicates that when 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 in which the contractor has acquired technical competence for his own commercial purposes, the contractor shall normally acquire title.

It would seem reasonable to conclude that some of DHEW contracts and grants would fall within this category. But recently the President's Patent Advisory Panel has indicated that if a contract is defined as falling within one of the four categories of Section 1(a)—the title section—it cannot fall within the category of Section 1(b)—the license section. This is true, even if the contract meet the criteria of both 1(a) and 1(b). In other words, the sections are to be applied consecutively, and where a contract falls within a section, subsequent sections will not apply.

Where does this bring us? It appears that the memorandum determines whether title to an invention should or should not be maintained by the Government on the basis of the purpose of the contract or grant from which the invention sprang. Moreover, it makes no distinction as to the stage of development the invention has reached. For example, if an invention was generated under a contract falling into the category of Section 1(b), title would reside in the contractor *even if the Government had completely financed its research and development, and the invention was ready for the marketplace.* On the other hand, if an invention were generated under a contract falling into one of the categories of Section 1(a), title would reside in the Government even if it

were shown that the invention needed further development, if the Government were unwilling to finance this development, and if an incentive were necessary to encourage the contractor to furnish the risk capital necessary to bring the invention to fruition.

The Department of Health, Education, and Welfare has a number of inventions which fall within Section 1(a) and which can be shown to need further development. For example, when compounds are synthesized by Public Health Service grantees, and the grantee's suggested therapeutic utility is confirmed by a screen, title to the resulting invention is vested in DHEW. It is clear that this type of invention is not ready for the marketplace until it has been licensed by the Food and Drug Administration. The acquisition of such a license requires the accumulation of an extensive amount of clinical data necessary for inclusion in a new drug application. A new drug application requires (1) extensive clinical data along with (2) toxicity data and (3) any data showing adverse side effects that develop in the course of clinical use. The Public Health Services does, under some circumstances, aid its organic chemists in bringing a potentially therapeutic compound to the point of commercial use by financing the acquisition of clinical data needed to support a new drug application. But in most situations, PHS's ability to aid its organic chemists is limited to the funding of the actual synthesis of the compound, providing or aiding in obtaining screens designed to distinguish possible useful from non-useful drugs, and possibly providing a small portion for the clinical data. The PHS-supported scientist who possesses a compound with a potential utility, and who would like to have it brought to the point of commercial use, finds, in most cases, that only the drug industry is able to accumulate all the data necessary for licensure.

tially therapeutic compound to the point of commercial use by financing the acquisition of clinical data needed to support a new drug application. But in most situations, PHS's ability to aid its organic chemists is limited to the funding of the actual synthesis of the compound, providing or aiding in obtaining screens designed to distinguish possible useful from non-useful drugs, and possibly providing a small portion for the clinical data. The PHS-supported scientist who possesses a compound with a potential utility, and who would like to have it brought to the point of commercial use, finds, in most cases, that only the drug industry is able to accumulate all the data necessary for licensure.

But the drug industry has refused, through the Pharmaceutical Manufacturer's Association, and, in some instances, individually to collaborate with our scientists

in bringing their drugs to the point of practical application without some guarantee of exclusive patent rights to compensate and protect their investment. This investment ultimately may amount, on the average, to between $200,000 and $500,000. Under present departmental policy, the President's Memorandum, and a 1924 Attorney General's decision,[8] the above guarantee cannot be given. This situation results in a serious loss of incentive to invest in the perfection and marketing of inventions supported by the Public Health Service.

Exclusive Licensing

If the Government is to require that title to health and welfare inventions reside in the Government no matter what stage of development the invention has reached, then the Departments and Agencies should be permitted to grant exclusive licenses as an incentive to draw forth the private risk capital needed to obtain public promotion and utilization of these inventions.

In any situation where it appears that non-exclusive licensing is ineffective to bring a Government-owned invention to the point of practical application and commercial use and where the Agency determines that such action is necessary in the furtherance of its mission, a Department or Agency should be able to grant exclusive licenses. Naturally, any such licenses would contain appropriate terms to safeguard the interest of the general public, such as march-in rights when it is determined the licensee is not fulfilling the public needs, and a provision insuring some period of unrestricted availability to the general public after the exclusive licensing period and before the patent expires. On the other hand, the purpose of such licenses is to obtain utilization of inventions which might not otherwise be used and therefore they should be designed to hold forth sufficient incentives to encourage prompt development and utilization of the invention in the civilian economy. For this reason, the licenses need not include a requirement for the payment of roy-

[8] *34 Op. Attorney General*, 320, 328 (1924).

alties to the Government, nor the requirement for the "grant-back" of a license for inventions made by the licensee in the course of his developmental work.

In DHEW, a policy enabling the granting of exclusive licenses in order to better fulfill its mission has been discussed with interest. It appears the initiation of such a policy is impeded by certain statements in the above mentioned 1924 opinion of the Attorney General's; those statements have generally been interpreted as holding that agencies may not grant exclusive licenses under Government-owned patents without specific statutory authority.[9]

In order to resolve this problem, it has been suggested that the Department of Justice be approached for a re-evaluation of the 1924 decision. It would be argued, at that time, that to stand by the interpretation of the decision is damaging to DHEW's mission. If this fails, the Department alternatively could approach Congress for statutory authority to grant exclusive licenses. This authority now exists in NASA and TVA, and such authority may be of greater importance to DHEW than to either of these two agencies due to the public health and welfare aspects of its inventions.[10]

If an active exclusive licensing program is to be undertaken, it should be conducted on a sound business-like basis and the various inventions

If an active exclusive licensing program is to be undertaken, it should be conducted on a sound business-like basis and the various functions should be performed by qualified personnel. This would require the expenditure

[9] *Ibid*, also see 38 *Op. Attorney General*, 534 (1935).

[10] The possible need for exclusive licensing authority in the various agencies has been brought to Congress's attention. Thus, in a 1959 preliminary report the Senate Subcommittee on Patents, Trademarks, and Copyrights stated:

> "In prior sessions, Congress has considered the question of licensing Government-owned patents, but no comprehensive legislation has heretofore been enacted on the subject. There is a growing need within the Government for authority to grant exclusive licenses in appropriate cases. For this reason the subject should receive serious consideration at this time." Patent Practices of the Government Patents Board, *"Preliminary Report on the Subcommittee on Patents, Trademarks, and Copyrights*, United States Senate, 86th Congress, 1st Session, 1959, p. 35.

of public funds both initially and annually, with returns being only of an intangible "public interest" nature unless royalties were collected.

Such a program would certainly increase the number of Government-owned patents, for unless the Government held patent rights it would have nothing to grant. Fewer waivers could be expected (where the agency has the authority to waive its rights to title in the invention upon certain findings), and more patent applications would be filed to support this program. One would be hesitant to let an invention go by unpatented and thus perhaps remain undeveloped, when, by patenting, the invention might become an important part of a licensing program which would result in commercial utilization of the invention. This all adds up to greater Federal expenditures of money, time, and more personnel.

Each individual patent would be assessed and evaluated to determine the commercial utilization potential of the patented invention.

An adequate publicity and promotional program would have to be developed, utilizing Government publications, scientific and professional journals, direct mailing, and personal contacts.

The selection of licensees would require close attention and information would need to be assembled on qualified prospects in various industries.

The negotiation of exclusive licenses would have to be [illegible] would require close attention and information would need to be assembled on qualified prospects in various industries.

The negotiation of exclusive licenses would have to be conducted carefully. In the preparation of licensing agreements consideration should be given to cross-licensing and patent pool practices prevalent in certain industries.

Provision would have to be made for the policing and prosecution of infringers, and also for the avoidance of infringement suits against the Government. In connection with the latter, an advantage of having authority to grant exclusive licenses is that the agencies would be able in certain cases to avoid or settle suits for infringement against the Government by entering into cross-licensing agreements.

The Public Health Service Act of 1944 contains many references to making available to the public the results of research. The mission of the PHS is to increase the amount of biomedical knowledge available upon which the practical betterment of human health can be based —the aims of the research are not achieved unless the benefits of Federal spending is available to the public.

Conclusion

Because the emphasis of DHEW is on basic research as opposed to developmental work, because great expenditures of effort and finances characterize the development of new drugs and medical instrumentation, and because no other field presents more urgent needs for all products to be brought to a point of utilization, study should be given to any possible mechanism offering promise as an inducement for the development of the products of research. Exclusive licensing of patents is one mechanism for achieving the highest possible rate of utilization for PHS technology.

The public Health Service is spending approximately $1 billion yearly on research and development. The majority of the knowledge and inventions produced by this program are disclosed to the public through publication in the hope that it will be exploited for practical applications. It is our hope that greater incentives can be developed to insure the use of all valuable discoveries.

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