DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201

July 13, 1978

OFFICE OF THE GENERAL COUNSEL

If you like your postal service you'll love our HEW Technology Transfer Program!

Howard Bremer — Pl. review — especially marked paragraphs.

MEMORANDUM

TO : Inspector General
Assistant Secretary for Legislation
Assistant Secretary for Management and Budget
Assistant Secretary for Planning and Evaluation
Assistant Secretary for Human Development Services
Commissioner of Education
Assistant Secretary for Health
Administrator, Health Care Financing Administration
Commissioner of Social Security

FROM : James Hinchman, Associate General Counsel

SUBJECT: HEW Patent Policy

I am enclosing for your review a copy of the draft memorandum we intend to submit in response to the Secretary's request that we conduct a review of the Department's policy concerning rights to inventions resulting from HEW-funded research.

I would appreciate receiving your comments by July 26.

cc:
Frederick Bohen

TRACER#6067

P-4000

HEW PATENT POLICY

INTRODUCTION

This paper, prepared in response to your request, addresses the policy of HEW regarding the disposition of rights to inventions made in the course of work done under HEW-funded research grants and procurement contracts. 1/ The decisions which you make concerning the recommendations we have set forth will not only determine the Department's own patent practices but will also form the basis of HEW policy in connection with the more general review of government-wide patent policy which has been undertaken by Congress and the Administration.

Our current general policy is to retain the right to determine disposition of rights to any invention made in the course of a research grant or procurement contract. Normally, our grants and contracts provide that such determination will be made after the invention is reported to HEW by the contractor or grantee. Once an invention is reported, HEW determines either that patent protection should be sought for the invention or that the invention should be made generally available by its "dedication" to the public. If we determine that a patent should be sought, it is our stated policy generally to require assignment of the patent rights

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1/ The only other inventions administered by HEW are those made by employees. Executive Order 10096 requires that these inventions be assigned to the government in most instances. The Commissioner of Patents was given the authority to issue regulations on this subject and they appear at 35 CFR 100. The disposition of these inventions is governed by the Federal Property and Administrative Services Act and by regulations promulgated by GSA appearing at 41 CFR 101-4. We have little discretion in dealing with these inventions, and our regulations at 45 CFR 7 are simply to implement the Executive Order.

to the government through HEW, once a patent application is made in the inventor's name. The contractor or grantee retains a nonexclusive license to use the invention, but may be granted greater rights in certain circumstances. Generally, these "greater rights" consist of either an exclusive license to practice the invention for a limited term of years or a conditional waiver of our right to take title to the patent, leaving the ownership of the patent to the grantee or contractor, or to the inventor.

This general policy is subject to one major exception, the Institutional Patent Agreement (IPA), which covers a substantial percentage of inventions resulting from HEW-funded research. The IPAs are agreements with nonprofit institutions that have approved patent policies, which permit an institution to exercise a first option to retain the rights to any invention made in the course of a research grant to that institution. Through HEW, the government retains a nonexclusive license to use the inventions and the right either to acquire title or to require licensing if the invention is not properly developed or if the patent rights are abused.

After considering the potential application to HEW of the alternative approaches currently being debated elsewhere in the Administration, we recommend that our present system of case-by-case determination of the disposition of patent rights be continued. In this connection, we also recommend improvement in the standards and procedures for awarding greater rights under HEW contracts and grants. Finally, we advise against

a precipitous decision to terminate the use of IPAs and suggest areas where data about the present system are needed before major changes are made.

BACKGROUND

While several agencies have statutes that authorize and regulate their dispositions of patent rights in varying degrees of detail, 2/ there is currently no government-wide statute that governs such dispositions by federal agencies.

In the absence of any other governing statute, HEW policies on patent rights to inventions made under grants or contracts in all areas other than coal mine health and safety research 3/ have been developed under the President's Statement of Government Patent Policy, issued first by President Kennedy in 1963 and modified in only minor respects by President Nixon in 1971. The basic purpose of this Statement was enunciated by President Kennedy as follows:

2/ The two most detailed statutes are those for ERDA (now part of the Department of Energy) and NASA. These statutes essentially provide that title to all inventions made under funding from these agencies be assigned to the agencies, which have the authority to grant greater rights when appropriate.

3/ The only statute that directly affects HEW determinations is part of the Federal Coal Mine Health and Safety Act of 1969. The Act provides that inventions made under contracts and grants for research on coal mine health and safety be available to the general public, with such exceptions and limitations as the Secretary finds necessary in the public interest.

> 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 nongovernmental 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.

The Statement, which applies to grants and contracts, outlines in broad terms the circumstances under which the government should acquire the principal rights and those under which greater rights should be left to the contractor.

For all government contracts for experimental, developmental or research work this Policy Statement is implemented in the Federal Procurement Regulations issued by GSA under statutory authority, which repeat the provisions of the Policy Statement and provide clauses for use in contracts. The regulations are mandatory with respect to contracts but "may also be used in grants .... as agencies deem appropriate." Agencies are permitted to implement and supplement the regulations, consistent with the FPR system; HEW's regulations

regarding dispositions of rights to inventions made in the course of grants and contracts are found at 45 CFR 8. 4/

The emphasis of the Department's approach to patents has shifted from a policy in the late 1950's which favored public dedication of HEW-funded inventions to the current policy of allowing grantees, upon request, to retain title to an invention or exercise rights greater than a nonexclusive license.

The change in policy, which was effectuated administratively, without alteration of the regulations, occurred after a series of internal memoranda from NIH in the early 1960s and a General Accounting Office study issued in 1968. The GAO study of the utilization of drugs formulated by grantees with NIH funding found that many potentially useful drugs were never developed beyond their initial formulation because without a guarantee of an exclusive right to produce the drug for a number of years, pharmaceutical concerns were unwilling to finance the extensive and costly clinical trials required by the FDA prior to marketing of the drug. A drug company generally would not underwrite this testing, the major component of the cost of a new drug, without some assurance that it would have the exclusive right to manufacture

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4/ A rule amending FPR to provide for government-wide use of IPAs in contracts with universities and nonprofit organizations was published in the Federal Register on February 2, 1978, but has been stayed because of the reexaminations of patent policy being conducted by Congress and the Executive. According to the OMB Administrator for Federal Procurement Policy, HEW would be required to adopt the terms of the agreement in the FPR if the rule is released.

the drug for a period of time sufficient to recoup that investment. Without such exclusivity, a competitor could also market the drug once FDA approval was obtained, with only a showing that the product was the same as that previously approved.

This rationale for granting exclusive licenses or waivers of rights on drug inventions is applicable to other situations where additional investment is required to bring an invention to the marketplace, and has led the Department to grant greater rights more freely in recent years.

OBJECTIVES OF HEW PATENT POLICY

Historically, the objectives of our patent policies have been to make inventions developed with government funding available to the public as rapidly and as cheaply as possible, goals which are sometimes incompatible.

While these objectives are basically sound, recent experience with the high cost of proliferating health care technology suggests that there may be circumstances in which the Department would wish to restrain or regulate the availability of a new invention. Recognizing this objective requires a broader statement of purpose--to influence the availability and cost of inventions made with HEW support, sometimes encouraging rapid, low cost availability, at other times restraining or regulating availability.

ALTERNATIVE BASIC APPROACHES

Our flexible current policy of case-by-case disposition of

patent rights derives from the President's Policy Statement and the GSA regulations. There are two alternative basic approaches to be considered--(1) dedication to the public of all inventions made with HEW funding, and (2) conditional waiver of all HEW rights to inventions made in the course of a research grant or procurement contract. Essentially the same options are currently being debated elsewhere in the Executive. The difficulty with both alternatives is their inflexibility in the face of the wide variety of circumstances the Department confronts in the disposition of patent rights.

The principal objection to returning to the dedication policy is that, as noted in the GAO report, many inventions arising out of HEW funding require further development to reach the market which we are not prepared to pay for. Without exclusive rights, no private company will undertake that development unless the costs are low enough to be easily recovered even if competitors market the invention without paying for the additional development, or unless the additional development can be protected, either as a trade secret or as a separate patent. As the drug patent example illustrates, such considerations may preclude development and marketing of an invention which requires additional, potentially unrecoverable investment.

The alternative of waiving all rights, leaving them to the contractor or grantee, has the obvious appeal that it encourages investment of private capital yet places no initial administrative burden on the agency. By removing the requirement that the agency

process applications individually, a policy of blanket waiver also tends to expedite further development of inventions made with HEW funding.

However, the costs of a policy of indiscriminate waiver may be unacceptably high. The argument for the waiver approach incorrectly assumes that, like drug compounds, all other inventions require substantial additional investment for development or testing before they can be marketed. Some inventions are immediately marketable, and/or do not require the incentive of exclusivity to attract private capital for development and marketing. In such situtations, waiver of all rights to an HEW-funded invention would bestow a windfall upon the contractor or grantee and, in some instances, would permit him to reap unjustifiably high profits on an invention made with public money.

There are other inventions which, while important in themselves, might be considerably improved if developed under competitive conditions. In addition, a contractor or grantee who lacks the capacity to develop an invention properly may nonetheless attempt to do so, delaying availability of the invention unnecessarily.

Finally, we believe the waiver approach should be rejected as a general policy because, while advancing the objective of expeditious marketing of inventions, it provides no means for the Department to monitor availabi[illegible], in situations where restrained or regulated development might be more appropriate.

RECOMMENDATION

For these reasons, we believe neither alternative approach is viable and therefore recommend that the current basic approach of case-by-case determination of the disposition of patent rights be continued.

Concur

Non-concur

IMPROVEMENTS IN THE CURRENT BASIC APPROACH

While we recommend retaining our current basic approach to the disposition of patent rights, there are, we believe, two areas in which our implementation of that approach can be improved:

1. Development of uniform, detailed standards and procedures for the awarding of greater rights under HEW grants and contracts; and

2. Reassessment of Institutional Patent Agreements.

1. Development of uniform, detailed standards and procedures for the awarding of greater rights under HEW grants and contracts.

As noted earlier, the disposition of patent rights under federal contracts is governed by GSA's Federal Procurement Regulations while separate HEW regulations govern the disposition of rights arising under Department grants. In general, the former permit waiver of title or the granting of an exclusive license only when necessary to call forth the private risk capital that is essential to bring the invention to the point of practical application. The Department's regulations, in contrast, permit waiver or exclusive licensing whenever it is in the public interest. Moreover, the FPR, while articulating a standard for the granting of greater rights, provide no criteria or procedures for determining when the standard is met.

To address the first of these problems, the Department's regulations governing the disposition of patent rights under grants should be amended to conform more closely to the provisions of the FPR. There are some differences between grants and contracts, of course. In most cases, grants are for basic research, are with nonprofit institutions, and provide that the grantee institution will share in the cost of the research. Contracts are more often for applied research, seek a more definite result, and generally are for work funded entirely by the government. Thus contracts would, usually result in the more fully developed inventions in which the public has a greater "equity." The FPR contain provisions that reflect these conclusions, and they could be addressed in more detail in the revised HEW regulations, if necessary.

The second problem can be addressed only by developing more detailed criteria and procedures for determining when greater rights should be granted under either a grant or a contract. Because the essential question is whether rights greater than a nonexclusive license are necessary to attract risk capital to bring the invention to the point of practical application, one approach is to publish a notice in the Federal Register before greater rights are granted indicating our intention to do so and soliciting offers to develop the

invention on a nonexclusive license basis. This is essentially the procedure followed under the Federal Licensing Regulations which govern the licensing to other than the inventor of inventions to which the government has taken title.

What results have this approach shown?

RECOMMENDATIONS

A. We recommend that the Department's regulations governing the disposition of patent rights under grants be amended to conform more closely to the Federal Procurement Regulations governing the disposition of patent rights under contracts, incorporating, in particular, the standard that greater rights are to be granted only when necessary to attract risk capital required to bring an invention to the point of practical application.

_____ Concur

_____ Non-concur

B. We recommend that more detailed criteria and procedures be developed for determining when the standards for granting greater rights have been met, including procedures for giving public notice of an intention to grant greater rights.

_____ Concur

_____ Non-concur

2. Reassessment of Institutional Patent Agreements

As noted earlier, the Institutional Patent Agreement is a major exception to our basic approach of flexible, case-by-case determination of the disposition of patent rights in identified inventions. The agreement gives an institution first option to take title to any invention which may subsequently be made under any grant from HEW so long as the agreement remains in force, subject to some conditions. Licenses granted by the institution under the patents it owns must be nonexclusive unless an exclusive license is necessary for development of the invention, a determination which is to be made by the grantee institution. In addition, royalties must be reasonable. The Department has the right to take over a patent if these conditions are not met or the patent is not developed.

There are currently over 70 such agreements covering grants with nonprofit institutions, most of them universities. Contracts are not covered by the agreements because IPAs are not permitted by the Federal Procurement Regulations that govern contracts. However, GSA has proposed amending the FPR to permit the use of IPAs for contracts.

These agreements reflect a policy judgment that if a nonprofit institution has a patent policy acceptable to the Assistant Secretary (Health and Scientific Affairs) and agrees to abide by certain conditions, the public interest will be

best served by allowing the institution to retain all rights to inventions made by its researchers. A major reason advanced for this is that inventions made under funding from HEW will be brought to the public much more quickly by avoiding federal administration and by giving the institution an incentive to speed development. It is assumed that, with these incentives, the institutions themselves can facilitate technology transfer and serve the public interest in administering their patents.

IPAs permit payment to the inventor of a percentage of any royalties, with the balance to be applied to the support of educational and research pursuits. By giving the inventor and the institution a financial stake in the patent, IPAs are said to promote reporting of inventions by academics who might otherwise merely publish (and thereby dedicate to the public) the results of their labors without notifying the Department or considering the potential benefits of patenting and licensing. In addition to the financial interest, the administration of the patent by the grantee encourages involvement by the inventor in the promotion of licenses, which may be necessary for successful marketing of the invention.

However, the use of IPAs is, in effect, the adoption of a waiver policy for a selected group of grantees, and is subject to some of the same criticisms as a waiver policy. It precludes case-by-case determination of the disposition of patent

rights in light of all the circumstances, can lead to windfall profits in some circumstances, and, most significant, results in surrender by the Department of its capacity to control the development of inventions made with its funds.

While there has been no overall analysis of specific inventions covered by IPAs, we may assume that because of their prospective nature, IPAs have given grantee institutions rights to some patents which might have been retained by the government had the inventions been subjected to case-by-case evaluation. Under IPAs, institutions may obtain the rights to inventions developed entirely by public money and may thus be allowed to earn royalties from a public investment.

A more serious criticism of IPAs is that they surrender governmental control of the economics and pace of development. While it is difficult to fully assess the economic impact of IPAs because NIH does not compile statistics showing the gains derived by grantee institutions, patent management agencies and licensees from licensing, the IPA system has a built-in bias toward exclusive licensing. An exclusive license is likely to be easier to market than several nonexclusive licenses and to be worth more in royalties to the institution and the patent management organization, which receives half of any royalties earned. The use of IPAs thus encourages exclusive licensing, without consideration of the interests of the taxpayer.

Moreover, by leaving to the grantee the first option to an invention, IPAs delegate to private institutions the Department's decision-making power over the desirability, method and pace of development of particular inventions. To this extent, IPAs sacrifice the broad objective of influencing the availability and cost of inventions made with HEW support to the more limited goal of encouraging commercialization. In our view, the use of IPAs is conceptually inconsistent with serving any objective other than rapid commercialization and with the case-by-case approach to dispositions of patent rights. However, IPAs have been in use for some time; they have substantial support within the academic community, and increasing government-wide acceptance. It would therefore be precipitous to recommend elimination of IPAs, particularly in the absence of a mechanism within the Department for efficient and effective administration of potential control over development. We do not now know whether the benefits to be derived from elimination of IPAs would justify the cost of the administrative mechanism required to exercise greater control and the potential disruption of relations with grantees.

In order to appraise the consequences of grantee administration of patents, HEW should undertake a study of patent applications and developments under IPAs to determine whether the Department

after the fact — cannot be made under the same conditions initial decision was made

would have opted for a different course of development had an IPA not been in effect. In addition, before deciding that the Department needs more control than IPAs allow over development of inventions, the Department should consider whether more vigorous exercise of its rights under current IPAs would provide an adequate degree of control at an acceptable level of cost. Finally, a broad opportunity for comment by parties outside the Department should be afforded before a decision is made concerning future use of IPAs.

who & how? Has this been done in Nelson hearings?

RECOMMENDATION

We recommend that you direct the Assistant Secretary for Health and the General Counsel jointly to undertake a reexamination of HEW use of IPAs. This reexamination should draw on extensive consultation with parties outside the Department, possibly by means of formal solicitation in the Federal Register of views and holding of hearings, and should be carried out with an awareness of the other related initiatives underway.

More taxpayer's money down the tube!

Concur

Non-concur