Draft

HEW PATENT POLICY

INTRODUCTION

This paper addresses the policy of HEW regarding the disposition of rights to inventions made in the course of work done under research grants and procurement contracts.[1] In theory, our approach to these dispositions is the same for both research grants and procurement contracts, but in practice they are treated somewhat differently.

Our general policy is to acquire the right to determine the disposition of rights to any invention made in the course of a research grant or procurement contract, with such determination usually made after the invention is reported to HEW by the contractor or grantee. Once an invention is reported, the first determination to be made is whether patent protection should be sought for the invention. If a patent is not desirable, the invention is published for any person to use. This is called "dedication"

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 on the how we deal with these inventions, and our regulations at 45 CFR 7 are simply to implement the Executive Order.

of the invention. Once it is determined that a patent should be sought, the stated preferred disposition of the rights to the patent is to require its assignment to the Government through HEW, once a patent application is made in the inventors name. The contractor or grantee retains a non-exclusive license to use the invention, but may be granted greater rights in certain circumstances. These "greater rights" generally are either an exclusive license to practice the invention for a limited term of years or a complete 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 that covers a substantial percentage of inventions made with HEW funding, the Institutional Patent Agreement (IPA). These IPAs are given to non-profit institutions that have approved patent policies, and permit the 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 non-exclusive license to use the inventions and the right to either acquire title or require licensing if the invention is not being properly developed or if the patent rights are abused. This latter right is often referred to as "march-in rights."

This paper will discuss the background of our current policy, current and potential objectives, the two alternatives to our current basic approach, and possible changes in the current approach. These possible changes include termination of the IPAs, making the standards for greater rights determinations applied to procurement contracts applicable to research grants, and applying these standards more strictly than in the past, revising our regulations, and supporting enactment of statutory authority for a licensing program. For each of these changes alternatives are presented for decision.

BACKGROUND

The basic emphasis of the Department's patent policy has shifted from a policy in the late 1950's which favored publication or dedication of inventions made with HEW's funding, to a policy of allowing grantees to retain title when they request it and of granting rights greater than a non-exclusive license when requested. The basic approach of the regulations governing these decisions has been the same and the difference in policy has been reflected in the administration of the regulations rather than the regulations themselves.

The shift in emphasis away from publication and dedicaton occurred after a series of internal memoranda from NIH in the early 1960s and after a General Accounting Office study issued in 1968. GAO conducted a study of the utilization of drugs formulated with NIH funding, and found that many

potentially useful drugs were never developed beyond their initial formulation because no company could be found to finance the required clinical trials without some guarantee that they would have the exclusive right to produce the drug for a certain number of years.

Once a new drug has been formulated and proposed for a specific use patent protection may be available, but the drug cannot be marketed. In order to obtain FDA approval extensive clinical testing is required. The cost of this testing is the major component in the cost of a new drug, and a drug company would generally not underwrite the cost of this testing without some assurance that it would have the exclusive right to manufacture the drug for a period of time sufficient to compensate it for underwriting that cost. If such exclusivity were not available, a competing company could also market the drug once FDA approval was obtained, having only to show FDA that its product was the same as that previously approved.

The reasons for granting exclusive licenses or a waiver of rights on drug inventions applies to many other inventions where additional investment is required to bring an invention to the marketplace. Our policy now is to grant such greater rights when this is the case, and our practice has been to make these grants of greater rights freely.

There have been many other studies conducted, both of government-wide patent policy and of the policies of individual agencies. The most comprehensive of these was a study conducted in 1966 by Harbridge House, Inc. for the Committee on Patent Policy of the Federal Council of Science and Technology. (This Committee is an interagency group that continues to have a role in shaping government-wide policy.) The latest attempt to change the policy for the government is the "Thornton bill", now pending before Congress. Among other things, this bill would give the first option to take title to all inventions made under government procurement contracts or research grants to the contractor or grantee, subject to certain "march-in" rights similar to those in the IPAs. Responses to this bill are providing the occasion for a new review of patent policy by many other agencies as well as HEW. Through the Federal Council of Science and Technology, there is a drive to formulate a uniform policy for the government, and one question to be considered is whether such a uniform policy is desirable given the differing missions of the agencies.

There is currently no government-wide statute that governs the disposition of patent rights by Federal agencies. Several agencies have statutes that regulate these dispositions in varying degrees of detail and which give the agencies explicit authority to make these dispositions. The two most

detailed statutes are those for ERDA and NASA. These statutes essentially provide that title to all inventions made under funding from these agencies be assigned to those agencies, with the agencies given the authority to grant greater rights when appropriate. The ERDA statute lists in considerable detail the criteria to be used in making these determinations. The NASA statute requires that hearings be held on the determinations, but the only criteria given is that a disposition of rights must be in the interest of the United States.

The only statute that directly affects HEW determinations is part of the Federal Coal Mine Health and Safety Act of 1969. At 30 U.S.C. 951(c) that Act authorizes contracts for research on that subject and provides that

inventions made under these contracts and grants be available to the general public.[2/]

Because there is no governing statute, determinations by HEW of patent rights to inventions made under grants or contracts, are governed by the President's Statement of Government Patent Policy, issued first by President Kennedy in 1963 and modified by President Nixon in 1971. The basic purpose of this Statement was enunciated by President Kennedy as follows:

> "... 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 is 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 outlined the circumstances under which the government should acquire the principal rights and under which circumstances greater rights should be left to the contractor. The Statement explicitly included grants in the definition of contracts.

2/ Our regulations on the subject, at 42 CFR 55.22, state that our general regulations at 45 CFR 8, apply. These regulations, however, appear to conflict with the statutory mandate to dedicate the inventions.

For procurement contracts this Policy Statement was implemented in the Federal Procurement Regulations at 41 CFR 1-9, which repeat the provisions of the Policy Statement and provide clauses for use in contracts. These regulations are mandatory and leave the Department little leeway in changing the policy they seek to implement. There are also regulations at 41 CFR 101-4 that regulate the licensing of government owned inventions to entities other than the contractor or grantee that developed them. They provide a more extensive list of considerations to be taken into account in a decision to grant an exclusive license and require that notice of the availability of the patent for licensing be given at least six months before any proposal to grant an exclusive license. Before an exclusive license can be granted, notice of intent to do so must be published and comments upon the proposal must be considered. They do not allow disposition of the entire patent, and any such action would be prohibited by the Constitution absent a statute authorizing such disposal. 3/

3/ In Public Citizens, Inc. v. Sampson (CA 74-303, D.C.D.C.), rev'd, 515 F.2d 1018 (D.C. Cir. 1975) the licensing regulations have been challenged on the basis that a grant of an exclusive license is also an unconstitutional disposition of property. The plaintiffs won the challenge at the District Court level but the Court of Appeals found that they lacked standing to raise the issue. The status of these licensing regulations remains in doubt.

There are no corresponding regulations covering inventions made under grants, although the President's Policy Statement applies to them as well. The Department's regulations regarding dispositions of rights to inventions made in the course of grants are found at 45 CFR 8.

OBJECTIVES OF HEW PATENT POLICY

The objective of the current policies is essentially to make inventions made with government funding available to the public, either by dedication of the inventions or by encouraging their commercial development when necessary. This is not the only objective that we can seek to achieve nor is it always the appropriate objective.

There are inventions made under our grants and contracts that have no clear potential effect on the public health or welfare. Gatorade is the best known example of such an invention, and there have been others. There is no reason for HEW to take any role in the development of these inventions. If they have no commercial value, they should be dedicated to the public, and if they have commercial value they should be sold in a way that will generate the highest income for the government. HEW is not equipped to perform this function, nor does it have the authority to do so. Such inventions should be passed to GSA to be disposed of as surplus property.

It is also possible that inventions might be made that could be harmful to the public welfare. We might wish to

suppress such an invention or to carefully regulate its use. We may also wish to regulate the use of beneficial inventions to achieve other objectives of HEW. The Department's recent report on Health Technology Management has suggested that patent licensing can play a role in HEW's initiative on health technology management. Among the factors that could be considered in licensing HEW patents are the cost at which they will be sold, the type of additional development to be taken by the potential licensee, or whether the potential licensee might be willing to license others to use similar or related patents owned by it. HEW does not currently have the capacity to implement to possible variety of policies that it might seek to implement through patent licensing, but establishing an office of technology management could give us that capability.

ALTERNATIVE BASIC APPROACHES

The flexible approach embodied in our current policy is virtually mandated by the President's Policy Statement and the regulations of GSA. Any initiative that we take must be within this framework. HEW should nevertheless formulate a position on whether to continue this basic approach, because of the Thornton bill and other possible initiatives outside the Department that could alter the basic framework. There are two basic alternative approaches, one being the dedication of all inventions made with HEW funding and the

other being to waive all rights to inventions made in the course of a research grant or procurement contract to the contractor or grantee. The waiver approach is the approach of the Thornton bill and of our current IPAs.

The principal objection to the dedication policy is that noted in the GAO report. Many inventions developed with HEW funds would not be developed unless we fund the additional development required. Without exclusive rights, no private company would do so unless the development costs are low enough that they could easily be recovered even when there are competitors who could market the invention without paying for the additional development, or unless the additional development could be protected, either as a trade secret or as a separate patent. The most serious example of this is drug patents. Because of this problem, this policy would find little support. While it could be implemented within the context of the President's Statement, our doing so would clearly be contrary to the spirit of that Statement.

The alternative of waiving all rights, and leaving them to the contractor or grantee, is not available to us in the current framework. This approach has the obvious appeal that it involves no initial administrative burden on the agency. It also tends to serve the purpose of expediting further development of inventions made with our funding, since the

contractors and grantees could immediately file a patent application on any invetion made and could begin to market it immediately thereafter.

The principal problem with the waiver approach is it assumes that all inventions are like drug compounds in that they require substantial amounts of money to be invested before they can be brought to the public. It also assumes that there is a public interest in bringing the invention to the public as rapidly as possible. Neither of these assumptions is necessarily always correct. Some inventions are immediately marketable, and the development of others is paid for by the public (this is particularly true at the National Cancer Institute which funds the clinical tests for many drugs). In either of these cases a contractor or grantee would receive a windfall if they were allowed to retain all rights, and in some instances would be able to reap monoply profits on an invention made with public money. These instances could not be common because most inventions that are made under HEW funding are somewhat esoteric, but there is no question that they would occur. A recent example was the CAT scanner developed by AS&E.

There are other inventions which, while important in themselves, might be subject to considerable improvement if development were under competitive conditions. An example of this is again the AS&E CAT scanner. There was enough

interest in this invention so that several companies were willing to develop and improve upon it without having an exclusive license. AS&E, had it retained a monopoly on this type of scanner, would have had little incentive to invest large sums of money to improve it. In a competitive market, however, they would have to compete not only as to price, but as to quality as well. The case of AS&E provides one additional example of the problem with a consistent policy of waiving rights, and that is that the contractor or grantee may not have the capacity to develop an invention properly but may nonetheless attempt to do so. AS&E has recently abandoned the scanner business after spending a year to enter the market.

Further, as noted above, HEW has several potential objectives to achieve other than the rapid development of the invention. Neither of the inflexible approaches would allow us to achieve these. A set of "march-in" rights that would meet all the objectives we could reasonably seek to achieve, would most likely prove to be more burdensome to administer than a system where the burden of justifying the need for greater rights is on the applicant. To attempt to achieve our objectives in this manner would likely result in considerable litigation, even if we were able to adequately review the performance of the patent holders. The strongest criticism

of the current flexible approach is that it is difficult to administer and that in the past we have taken so long to make the determination of rights that we seriously impeded the development of the inventions. This need not be the case however, and establishing an office of technology management would be one possible way to provide the capacity to overcome this management problem.

RECOMMENDATION

We recommend that the current flexible approach be continued and that the Department oppose any efforts to adopt the two alternative inflexible approaches.

Concur _____ Non-concur _____

CHANGES TO THE CURRENT APPROACH

Within the framework of the approach of the President's Policy Statement, and the Federal Procurement and Licensing Regulations, there are several possible changes in policy to be considered, although some of these changes would conflict with the details of those documents and require approval outside HEW. In this latter category are changes which would bring into licensing determinations, considerations other than those included in the Federal Regulations which relate primarily to commercialization of inventions. These changes would likely require approval outside the Department or special legislation. Since the formulation of those other objectives should be made by other operating components of HEW, this paper will not make specific recommendations on that subject, but will recommend that such additional objectives be considered and incorporated into our patent policy.

There are, nevertheless, changes to be considered that might better achieve our current objectives and other developed in the future. Those to be addressed are:

1. Applying to research grants the same standards for determinations of greater rights applicable to procurement contracts;

2. Termination of the Institutional Patent Agreements;
3. Revision of the HEW Patent Regulations;
4. Developing clearer standards and better procedures for determination of rights to inventions made with HEW funding; and
5. Seeking statutory authority.

1. Applying to research grants the same standards for determinations of greater rights applicable to procurement contracts

The President's policy statement makes no differentiation between grants and contracts. The requirements of the statement apply to both. There are differences between them, however, and arguments can be made for different treatment, although this must be within the context of the President's Statements. Grants usually contemplate the grantee institution sharing in the cost of the grant, are usually for basic research, and are always with non-profit institutions. The arguments for treating non-profit entities in a different manner from profit makers will be discussed in the context of IPAs. Contracts are more often for applied research, seeking a more definite result, and unless special provisions are made the government pays the entire cost of the work. Thus contracts would, on the average, result in the more

fully developed inventions where the public has a greater "equity." The Federal Procurement Regulations take these factors into account and applying them to grants as well as contracts would likely result in different average results for each class, but only when this different result is justified. In addition, this would better serve to implement the President's Policy Statement. In the past this would have had the effect of automatically eliminating the IPAs, but this is no longer the case since the FPRs now allow such agreements.

There are also other considerations we would want to take into account in determining the rights to patents than are listed in these regulations. Some of these might nevertheless be permissible, and these could be set out in a revised version of our own regulations. For those that would conflict with the regulations, we would require an approval of the deviation from GSA, or perhaps separate statutory authority.

2. Termination of Institutional Patent Agreements

Since the GAO study in 1968, HEW has expanded its use of Institutional Patent Agreements and has adopted an uniform agreement. There are currently over 70 institutions that have such agreements with HEW. The National Science Foundation also makes wide use of these agreements. There

is widespread support for these agreements, both within HEW and outside the Department, in other agencies and among research institutions. GSA has just promulgated a regulation allowing agencies to use such agreements with non-profit institutions to cover inventions made under research and development contracts.[4/]

IPAs are not mentioned in the President's Policy Statement, and they depart from the approach of the Statement in that they automatically waive the rights of the government to all inventions made under grants made through a given institution. Nevertheless, because their use has found such widespread approval, the question of whether to continue the IPAs should be considered as a policy question and not on the basis of whether they are authorized by the President's Policy Statement. We currently have IPAs with 72 institutions, with other agreements pending. The agreements amount to an adoption of the waiver policy for these institutions, with certain restrictions on their administration of the patent rights. The agreements give the institution first option to take title to any invention made under a grant from HEW. The agreement provides, among other things, that licenses to use the invention shall be non-exclusive unless an exclusive

---

5/ 43 Fed. Reg. 4424 (1978) (Amendment to 41 CFR 1-9).

license is necessary to have the invention developed, and limiting the term of such a license. There are also restrictions against unreasonable royalties. The agreements give us "march-in rights" if these conditions are violated or if the invention is not developed.

These agreements reflect a policy judgment by the agency that in the case of research agreements with non-profit institutions, if the institution has an acceptable patent policy and agrees to abide by certain conditions, that the public interest will be better served by allowing the institution to retain all rights to inventions made by its researchers. The major reason advanced for this is that inventions made under funding from HEW will be brought to the public much more quickly this way, and that the institutions can be trusted to serve the public interest in administering their patents. The march-in rights are included to protect the public interest should this latter assumption prove incorrect. Another reason for the adoption of these agreements was the problems caused by the slowness of the Department in responding to requests by grantees for greater rights, and the resulting criticism by GAO.

The IPAs are, however, subject to all the same criticisms as the waiver policy. The IPAs adopt the waiver policy for a certain group of non-profit institutions, leaving other grantees and contractors to be governed by the standards in

the President's Statement. One question that must be addressed is whether this difference in treatment between non-profit and profit making entities can be justified. One of the reasons for this distinction was noted before. There is an assumption that non-profit institutions can be trusted to protect the public interest and that profit making entities cannot. Another justification is that any royalties received by the institutions will be put into research, so that the windfall argument does not apply. The IPAs require only that the money be used for educational or research pursuits and allow the inventor part of the royalties. In addition, many institutions administer their patents through patent management companies that share the royalties. These reasons for the distinction between non-profit institutions and profit makers are not particularly strong.

The other arguments in favor of the IPAs are not necessarily limited to non-profit institutions, but some are based upon situations that are more likely to arise in such institutions. One of these arguments is that the IPAs encourage better reporting of inventions. Most of the inventions made with HEW funding are made under grants for basic research. The researchers are academic persons whose primary bias is in favor of publishing results of their investigations. Many of them are not concerned with commercial development of the inventions, especially since they would not get benefits

from this development. One of the problems noted in the GAO study was that investigators would formulate a promising new drug and publish their findings without reporting the invention. Once an investion is publicized, an application for a patent must be filed within one year of the publication or the application is barred. The IPAs give institutions an incentive to monitor their investigators and to encourage patent applications where appropriate. Researchers, however, also have an interest in seeing their inventions put into use and most researchers can be relied upon to report inventions so that they will be developed. Project officers can also be instructed to see that inventions are reported, although the Department's experience in relying upon project officers to enforce business requirements has not been entirely satisfactory in the past.

One of the effects of the IPAs is to delegate the agency's responsibility for determining whether it is necessary to give a commercial developer exclusive rights to an invention in order to get it to undertake its development. The IPAs require non-exclusive licensing unless exclusive licenses are necessary to develop the inventions. (The standards for this determination are, however, broader than those of the President's Policy Statement.) This is the most serious defect of the IPAs in that the institutions

are in no better position to determine this than we are, and they have a strong incentive to issue exclusive licenses. A company could be expected to pay much more for exclusive rights than for non-exclusive rights, and in some instances the value of one exclusive license may exceed that of the non-exclusive licenses that could be issued. Many institutions employ patent management organizations to administer their patents and these companies, whether or not they are profit-making, exist on their share of the royalties. They have no incentive to protect the public interest. The determination of whether to give an exclusive license is in effect left to the patent management company, since they test the market for the institution as part of their responsibility of managing the patent.

If the IPAs were terminated, we would have to substantially expand the staff now managing the Department's patents. Just processing the petitions for greater rights on an individual basis would require an expanded staff. This is not, however, a good reason for abandoning our responsibilities if they are not being met by the IPAs. As noted previously, establishing an office of technology management could alleviate this problem.

The IPAs suffer from the same inflexibility as does the waiver approach, and they necessarily imply a distinction between contractors and grantees that is not logically defensible. If the Department is to take a larger role in health technology management, continuation of the IPAs would eliminate many opportunities to use patent licensing to do so. The inventions made under grants covered by IPAs constitute a major portion of the inventions made with HEW funding. Many of these inventions are rather esoteric and their development would require the active participation of the inventor as well as a vigorous promotion effort, and these could reasonably be left to the institutions to develop. But some inventions would be important enough to warrant our management, and the only clear reason for allowing the institutions to retain title to these is that the administrative effort required to differentiate between these two classes of inventions is too great.

RECOMMENDATION

There are three courses of action that can be taken, one being to decide to continue the IPAs for the time being, and another being deciding to immediately terminate them. We recommend the third alternative of announcing that we are considering terminating them, once an office of technology management is established, and soliciting comments on that proposal. Because of the popularity of these agreements, and because HEW in the past has spearheaded the use of such agreements in the Federal Government, we do not recommend that any action to terminate them be taken without careful study and opportunity for comment.

Alternative 1: Continuation of IPAs

_____ Concur _____ Non-concur

Alternative 2: Termination of all IPAs

_____ Concur _____ Non-concur

Alternative 3: Announce intent to consider termination of the IPAs and seek comments

_____ Concur _____ Non-concur

3. Developing Clearer Standards and Better Procedures

As currently administered, our current policy amounts to a virtual adoption of the waiver policy, even though it is articulated as a flexible approach favoring title in the government and non-exclusive licensing. As noted previously, whenever a party has asked for rights greater than a non-exclusive license it has received what it asked for. While administrative changes have alleviated this problem somewhat, the lack of clear standards and adequate procedures has hampered this effort.

Assuming that the standards of the Federal Procurement Regulations are applied, most applications for either waiver of title or for an exclusive license will hinge on whether that grant of greater rights is necessary to call forth the private risk capital to bring the invention to the point of practical application. In most circumstances this means that some measure of exclusivity is necessary to get a company to invest enough money to bring the invention to the marketplace. There are no standards for determining this and no mechanism for testing assertions by applicants, except in the Federal Licensing Regulations. These regulations require that if an exclusive license to a government-owned invention is proposed, notice of intent to issue such a license must be published

in the Federal Register and parties given an opportunity to comment and apply for non-exclusive licenses. This serves the purpose of inquiring whether there are other parties interested in developing the invention without an exclusive license.

This procedure of notice could be applied to all greater rights determinations or at least to those where we suspected that there might be some outside interest. This would pose two problems, neither of them insoluble. One is the administrative problem posed and the necessary expansion of staff. The other is the problem caused by publication of an invention prior to a patent application. If we were to publish a notice of intent to grant an exclusive license to an invention, we would have to make a full description of the invention available for inspection. If this took place more than a year prior to a patent application, that application would be barred. Applicants for greater rights under grants and contracts are currently allowed to apply for a patent, once a determination is made to patent a reported invention. They are told, however, that if the greater rights are not granted, they will not be reimbursed for costs they incur. Our past readiness to grant such requests for greater rights made this an unimportant consideration, but a change in that policy would make the applicant more reluctant to file an application until the rights are determined. The most

sensible solution to this would be to make the patent application an allowable cost under the grant or contract, once the application for a patent had been approved, unless the contractor or grantee were allowed rights greater than a non-exclusive license.

One other problem that should be addressed is a provision of the Federal Procurement Regulations that exempts cost sharing agreements from the mandatory nature of those regulations, although it urges that they be followed as closely as possible. This would be a major problem if we applied those regulations to grants, since grants by definition include a certain degree of cost sharing. There are no standards given for determining when this exemption applies, or for determining rights to inventions made under cost sharing agreements. Even if we determined that a contractor or grantee should retain title to the invention because of the cost-sharing, we would want to obtain guarantees that the patent rights would not be abused.

RECOMMENDATIONS

Once our future policy is defined, our regulations should provide clearer guidance in administering that policy than they have in the past. There are however, three decisions that can be made now, assuming that we continue to have a policy where greater rights are determined on a flexible basis.

Recommendation A:

Impose a requirement that notice of intent be given and comments sought before any determination to grant an exclusive license or to waive all rights is made. There are two alternatives to do this.

Alternative 1:

Require publication of a notice of intent to grant greater rights in all instances where we initially propose to do so.

_____ _____

Concur Non-concur

Alternative 2:

Require notice of intent for all proposed grants of greater rights except in those cases where the official making the determination finds that the evidence before him is adequate to determine that the grant of greater rights is necessary.

_____ _____

Concur Non-concur

Recommendation B:

That standards for determining whether the cost-sharing exemption applies be drafted as well as standards for determining rights to inventions made under cost-sharing agreements.

_____ _____

Concur Non-concur

Recommendation C:

That we establish a means to reimburse a contractor or grantee for the costs of a patent application, once such an application is approved, if an application for greater rights is denied.

Concur _____ Non-concur _____

4. Revision of HEW Patent Regulations

Whether or not any changes are made in the Department's patent policy, the Department's regulations must be rewritten. They are badly out of date and in some respects conflict with the President's Patent Statement and the Federal Procurement and Licensing Regulations. They do not accurately reflect the current delegations of authority to administer the Department's patent program. They state that the Assistant Secretary for Health is responsible for all patent determinations, although part of this responsibility has, for some time, been delegated to the Office of the General Counsel, with the Assistant Secretary for Health responsible only for determinations with major policy significance.

Licensing of government-owned inventions (those that have already been assigned to the Department) are governed by detailed regulations issued by the GSA noted above. Our regulations treat this matter very briefly at 45 CFR 6.3 without referring to those regulations, and impose only the standard that a grant of an exclusive license be in the public interest. These regulations should be rewritten to incorporate the Federal Licensing Regulations, and to provide a mechanism for the hearing of appeals on decisions under those regulations as they require.

Our regulations at 45 CFR 8, pertaining to determination of rights to inventions made under grants and research contracts are more seriously deficient. They do not refer to the Federal Procurement Regulations which are mandatory as to procurement contracts, and provide for the application of procedures and standards which are very different from those required under the FPR. Nor do our regulations refer to, or reflect, the standards mandated by the President's Policy Statement. The standards given in our regulations are much less strict than those of the FPR and the Statement. They provide that title shall be assigned to the United States unless the Assistant Secretary finds that the invention will be dedicated by the institution or made available by them for non-exclusive licensing by them, or unless he finds that the invention will be more adequately and quickly

developed for widest use by assigning the patent to a competent organization for management. This conflict in regulations is not an abstract problem, and has caused problems in making these greater rights determinations. We have previously recommended that the Federal Procurement Regulations be made applicable to our grants, but even if this recommendation is not accepted they should be applicable to all procurement contracts and this should be stated explicitly. The standards given for determination of greater rights under grants should reflect those standards given in the President's Statement.

In addition, there is one provision, of our regulations relating to cancer chemotherapy industrial research contracts, at 45 CFR 8.7, making our other patent regulations inapplicable to them. This was done because NCI had trouble attracting contractors without a determination of rights to patent at the time of contract award. This procedure is permitted by the FPRs. If this practice is still necessary, our regulations should be rewritten to state that for this class of contracts a determination has been made that extraordinary circumstances exist justifying the determinations of rights at the time of contracting, which was the purpose of the original regulation.

While the regulations should be rewritten, this process should await decisions and possible changes to our policy and decisions on any changes in the administration of that policy. Once these matters are decided, clearer standards for these determinations should also be formulated so that policy decisions can be more effectively implemented.

RECOMMENDATION

The Department's patent regulations should be completely rewritten once the other issues presented by this paper have been decided.

Concur _____ Non-concur _____

5. Supporting Enactment of Statutory Authority for a Licensing Program

As noted previously, several Federal agencies have statutes granting them authority to administer patents developed with their funding. If HEW decides to take a stronger role in managing the technology developed with our funding, the Department may need special statutory authority. The Federal licensing regulations are of doubious constitutionality, and while the Justice Department supported them in the Public Citizen cases, officials there have voiced doubt as to their validity. This doubt is shared by many

others within the government. If we took a larger role in managing our inventions, it is likely that we would take title to many more than we do now. Indeed, if we were to administer the current standards more rigorously we would be taking title to more of them. It would be better to have clear authority to grant more than a non-exclusive license, since a company might be reluctant to commit large sums of money to an invention if their exclusive license is subject to constitutional challenge.

In short, our entire licensing program is on a very uncertain foundation, and we should support enactment of a statute giving authority to grant licenses other than non-exclusive ones, and perhaps to dispose of patents if the public interest can be served by that disposal.

In such a statute it would also be desirable to include authority to pursue a variety of objectives, listing as many as possible, so that our attempts to do so would not be challenged.

RECOMMENDATION

That the Department support enactment of a statute reflecting our policy objectives and authority to pursue them, once the decisions are made defining these objectives.

Concur _____ Non-concur _____