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I N D E X

THE PATENT POLICY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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I. Preface

Government patent policy is probably one of the most arcane topics that confront the Government and the public. Notwithstanding, evidence indicates that failure on the part of the science administrators to understand this topic greatly reduces the prospect of the Department programs under their auspices reaching a successful result, since it is an integral part of technology management.

II. Innovation and the Life Sciences

A. In General

Before any recommendations can be formulated on how innovation in the life sciences should be managed, a basic understanding of the innovative process would be helpful.

It is important to recognize that inventions are not generally "flashes of genius" which provide instant solutions to difficult social problems, but are more likely a system of costly incremental developments taking anywhere from five to fifty years before understood, accepted, and widely adopted. Few great innovations emerge under imposed time constraints no matter what resources are brought to bear in their development. In addition to overcoming technical difficulties, innovation is often confronted by social hostility due to disruption of accepted and comfortable means of social conduct.

Because of the long and costly development periods necessary to overcome technical hurdles and social hostility which innovation must sometime overcome, the presence of a highly trained, diligent, enthusiastic, nearly obsessive, individual who will advocate a particular innovation is necessary if the innovation is to be brought to fruition.

Since adequate resources are a fundamental part of successful innovation, such individuals are ordinarily found in organizations willing to devote such resources to satisfy the innovator's desires. While large corporations have all the resources necessary to satisfy the innovator's needs, generally these resources are not utilized to support long range innovation, since it is alternatively easier for such a corporation to make a profit in the short and medium term by spending on advertising and improving manufacturing processes. This appears to be the reason why innovation is not ordinarily championed effectively in large corporations (for example, the so-called "smoke-stack industries").

B. The Life Sciences

While the innovative process in general is complex, for the reasons stated above, Government regulation of many life science innovations adds an additional barrier of enormous proportion that must be overcome by the innovating entity. (Attachment A diagrams

the costly development route from genesis to use of a potential new therapeutic agent.) This additional barrier is even more formidable to the innovator employed by the Government, a non-profit organization, or a university, all of which cannot unilaterally command the resources that must be forthcoming from the industrial sector in order to bring their innovations to fruition. With over 3 billion dollars being utilized by Government, nonprofit and university laboratories for research in the life sciences, the need for policies that enhance collaboration between such laboratories and industrial developers who can commercialize end results seems apparent.

The difficulty in nurturing the enormous leap of fundamental ideas from such laboratories to industrial development has been clearly recognized by the operating agencies of this Department, as will be apparent from review of this report. The assertions throughout the December 22 report on "Health Technology Management" to the contrary, are deemed to be in error as well as that report's recommendations to solve what it perceives to be the problem.

III. Historical Evolution of Department Patent Policy and Practice

A. Pre-1962

On April 11, 1953 the Federal Security Agency and other related agencies were consolidated into the present Department of Health, Education and Welfare (Reorg. Plan No. 1 of 1953). The patent regulations of the Federal Security Agency (Attachment B) served as

the model for the Department's existing regulations (45 C.F.R. Parts 6-8) (Attachment C). The Department regulations have not changed philosophically from their beginning years, although they have been modified in order to bring them into compliance with overriding suggestions from the President's Statement of 1963 and amendment to the Statement in 1971 and in areas requiring special attention. However, because of the discretionary nature of the regulations, practice under the regulations was not consistent until recent years.

In general, 45 C.F.R. Part 8 of the regulations provides to the head of the agency, when allocating rights to inventions generated in the performance of grants and contracts, the discretion to:

1) Enter into agreements with nonprofit organizations, leaving to that organization a first option to future inventions made in performance of Department grant support if the Department deemed the organization's patent policy to be consistent with the Department's aims and the public interest (45 C.F.R. 8.1(b)). These agreements are commonly referred to as Institutional Patent Agreements (IPA's) and are viewed as an important part of the Department's technology transfer program. (Within the period between 1954 through 1958 eighteen such agreements were executed. The terms of those agreements were not uniform, and in some instances inconsistent.)

2) Determine to permit an organization (whether or not for-profit) to retain rights to identified inventions made by

such organization, under either grant or contract on the basis of equity or the need to encourage the investment of risk capital and expeditious public use in situations where the organization has no IPA (45 C.F.R. 8.1(b) and (d), and 8.6).

In 1958 the regulations were amended to permit commercial concerns to retain the first option to future inventions when conducting research and development under contracts in the limited area of cancer chemotherapy drug research in order to assure the participation of the most qualified pharmaceutical firms (45 C.F.R. 8.7). This was deemed necessary, as strong indications were made that industry participation would not be forthcoming without such an amendment. This exception has been denied to newer drug development programs in the National Institute of Drug Abuse and the National Institute of Child Health and Human Development. Operating personnel of the Institutes have advised that industry participation has been difficult to obtain due to the Institutes' inability to guarantee rights to future inventions.

45 C.F.R. Part 7 of the regulations parallels and incorporates by reference Executive Order 10096, which governs allocation of inventions made by Government employees. Since the Executive Order covers all the agencies of the Executive Branch, allocation of employee invention rights is not deemed a subject of the same concern as allocation of inventions generated by grant or contract. It is clear

that the Executive Order is not one which the Department could effectively change without agreement of the other research and development agencies and the President. Accordingly, disposition of employee inventions between the Department and its employees will not be discussed at length, other than noting that substantially all dispositions result in Department ownership. Further, the employee inventions to which the Department obtains ownership are a major portion of the Department's patent portfolio and, therefore, the subject of much of the Department's licensing program under 45 C.F.R. 6.3 and the Federal Procurement Regulations covering licensing of Government-owned inventions.

In 1965 the Federal Council for Science and Technology (FCST) report on Government Patent Policy determined that the Department's Institutional Patent Agreement program was consistent with the President's Statement, 1965 Annual Report on Government Patent Policy, FCST at page 16 (Attachment D). Further, the treatment of industrial contractors under the cancer chemotherapy program also has been considered consistent with the exceptional circumstances exception of the President's Statement as it was implemented by the Agency head after careful consideration.

B. The 1962-1968 Period

In 1962 the first suggestion appeared that the discretion left to the Department within its regulations to permit grantees and

contractors to retain invention rights was not being utilized. This was perceived to be a problem that would ultimately adversely affect the Department's ability to bring its research results to fruition and public use. In a 1962 memorandum (Attachment E) from Dr. Kenneth Endicott, the Director of the National Cancer Institute, to the Surgeon General of the Public Health Service (now the Assistant Secretary for Health), Dr. Endicott suggested that the Department had acquiesced to a doubtful thesis that Government-generated inventions would be utilized if placed in the public domain (the equivalent of nonexclusive licensing or dedication to the public). He suggested that this policy was acceptable to the Department, since

> "it has found some approbation in the Congress,"

notwithstanding that

> "the policy does not permit an agreement in advance on the disposition of patent rights in a collaborative research program involving support from PHS and other agencies and organizations."

While it is clear that Dr. Endicott's characterization of Department patent policy at that time could be confirmed by a historical review of the period, one need look no further than the suggestion by Attorney General Rogers to President Eisenhower to determine the mood of policymakers in these years:

> "The public interest will best be served by opening government-owned inventions to general public use, without discrimination or favoritism among users.
>
> "While opinions vary, the weight of experience is that government-owned technology can, for the most part, be exploited to a satisfactory extent under a system of non-exclusive licensing or public dedication. In the occasional situation where commercial use and exploitation of worthwhile inventions is discouraged by the need for a substantial investment in promotion, developmental and experimental work, with the attendant risk of loss, the government should finance such operations, in whole or in part, to demonstrate or prove the commercial value of the invention. This method of encouraging the use of the invention is preferable to the grant of an exclusive license.
>
> "As a basic policy, all government-owned inventions should be made fully, freely and unconditionally available to the public without charge, by public dedication or by royalty-free, nonexclusive licensing." (Emphasis added.)

The records of the Patent Branch do not indicate whether any action was taken on Dr. Endicott's recommendations to study the consequences of Department patent policy as administered at that time.

By 1964 the accuracy of Dr. Endicott's remarks became more apparent as specific cases began to emerge where it was clear that a guarantee of some patent protection was necessary to obtain the risk investment of an industrial collaborator to bring potential life-saving innovations into public use. In a memorandum (Attachment F) from the NIH Director to the Surgeon General, the Director, first citing the Endicott memorandum, indicated that the discretion of 8.2(b)

> "has not been used in approximately five years, and proposals which have been advanced for Department approval have invariably resulted in decisions to keep title in all reported inventions with the Federal Government."

He followed by indicating that

> "This situation results in a serious loss of incentive to invest in the perfection and marketing of PHS supported inventions"

and continued to list specific examples that had reached a point of impasse in development due to the absence of a determination to release some patent rights.

The Deputy Surgeon General forwarded this memorandum to the "Department Patent Officer" (one of the responsibilities then assigned to the Assistant General Counsel for Business and Administrative Law) (Attachment G). In this memorandum the Deputy Surgeon General indicated that

> "We have recognized this problem for a considerable period of time and believe we cannot afford to let it go unresolved much longer."

In addition, the memorandum lists additional examples and continues that these examples

> "emphasize that our policy does not facilitate arrangements for bringing to bear the risk capital and technological know-how of the private sector. As you know, I concur in the point of view that it is preferable to create conditions that will attract private initiative rather than to undertake complete Government financing of the cost of research and development of all inventions that grow out of the Government's programs." (Emphasis added)

It appears evident that the Deputy Surgeon General's comments cannot be reconciled with the recommendation of Attorney General Rogers to President Eisenhower, noted above. It should be noted that substantially all of the inventions generated through Department support fall within

the category Attorney General Rogers identified as "the occasional situation" (see Rogers' quote on page 8), and that development of the nature suggested would have required a substantial increase in the Department's budget.

The records of the Patent Branch indicate that though two of the examples listed were later favorably acted upon, the action occurred after industrial interest had been withdrawn. There is no indication of the action on the remaining examples. None of the innovations involved has ever been delivered into public use, and the public's investment in generating these inventions plus the alleviation of suffering they may have prevented appear lost forever.

On August 17, 1965 the then Director of NIH, Dr. James A. Shannon, testified before a subcommittee of the Senate Committee on the Judiciary on the uncertain state of Department patent policy at that time (Attachment H). In short, Dr. Shannon indicated that:

> "The uncertainties involved in after-the-fact determinations have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application."

This statement covered all innovations generated with Department support, whether the source was a Department employee, grantee or contractor, since the ultimate conduit to public use for all these innovations in our present society is the industrial sector.

It should be further noted that Department records indicate that 33 requests for Institutional Patent Agreements, dating from the last IPA executed in 1958, were pending at the end of 1966.

The Department's reluctance to utilize its discretion to relinquish patent rights to grantees and contractors during this period resulted in a number of cases in which investigators, recognizing that further development of their inventions would not be undertaken without the ability to transfer a patent right, filed patent applications without the consent of the Department and unconditionally assigned them to commercial concerns willing to undertake further development. Illustrations of this phenomena were the "Gatorade" and "5FU" cases. The Department now has pending in the Department of Justice a request to take action to retrieve rights to a series of inventions made during the 1960's by an NIH grantee investigator who unconditionally assigned these rights to a corporation for over a million dollars. These cases have occurred without the knowledge of the nonprofit organization involved and are presumed to have happened due to the well known attitude of the Department regarding release of patent rights in the 1960's.

The long period of uncertainty over use of the discretion to allocate inventions resulting from Department-funded grants and contracts to the innovating organization was brought to a close by the GAO report B-164031(2) of August 14, 1968, "Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry" (Attachment I). In summary, this report, based on extensive interviews with NIH grantees and others, concluded that the pharmaceutical industry would not utilize its risk capital to pursue further development of innovations generated at Department

expense without a guarantee of some patent exclusivity. In some situations the GAO discovered investigators with hundreds of compounds with potential therapeutic value on their shelves with no source to test their potential. The GAO criticized the Department for its failure to utilize the discretion of its regulations in either entering into institutional agreements (8.1(b)) since 1958 or making timely determination of rights to requests for greater rights after identification of an invention (8.2(b)) and (d)). In reponse to this criticism James F. Kelly, Assistant Secretary, Comptroller, DHEW, indicated by letter of March 20, 1968 (copy in rear of Attachment I) that the Department had identified the problems of concern to GAO and was moving to:

1) generate a uniform IPA for use with qualified institutions and
2) expedite processing of requests for greater rights to identified inventions from grantees or contractors without IPA's.

C. The Period After the August 12, 1968 GAO Report.

Although it is clear from the records provided that the perceived failure of Department management of patents stemmed from adoption by elements of the Department of an unworkable concept espoused by the Department of Justice and some members of Congress, it must be noted that in part it was also based on organizational problems. Briefly, these problems were resolved through two different reorganizations that

resulted in the present consolidation of operating responsibilities in the General Counsel's office and policy consideration in the Assistant Secretary for Health and the operating agencies. The responsibilities of each organization are detailed in the "Department Patent Activities," Chap. 1-901, Dept. Org. Manual May 27, 1969 (Attachment J). Although organizational problems remain (possibly due to the failure to recognize that the patent staff is primarily a program function with initial responsibility for management of Department generated innovations with legal functions, rather than a legal function with minor program functions), it appears that the relationship has been successful, since each element has striven to establish a Department image conducive to encouraging the collaboration deemed necessary between Government, universities and industry. It is suggested that a closer look at organizational problems would appear to serve a more useful purpose than reexamination of Department patent policy, especially in light of its near universal acceptance by the nonprofit sector which is the recipient of the major portion of the Department's R&D budget and the Institutional Patent Agreement's identifiable influence in increased technology transfer. In that regard both the Association of American Universities in response to Secretary Califano's "Operation Common Sense" (Attachment K) and the Commission on Federal Paperwork (Attachment L) have requested that the Department continue to spearhead the use of the HEW institutional patent agreement policy within the remaining agencies of the Executive Branch.

With the reorganization of 1968 accomplished, the Department acted to terminate the 18 IPA's in existence since 1955 and substituted the new uniform IPA of 1968. The uniform IPA was developed in collaboration with the patent staff, operating agencies, Assistant Secretary for Health and Scientific Affairs and Deputy Secretary after a number of meetings involving all these elements. Development and implementation of the uniform IPA, of course, was intended to satisfy Assistant Secretary Kelly's indicated course of action to GAO. Since the execution of the first uniform IPA on December 31, 1968, the Department has executed a total of 72 IPA's. (The uniform IPA and the 72 universities and nonprofit organizations functioning under the Agreement are enclosed as Attachment M).

As the virtues of the HEW IPA program became apparent in practice, the nonprofit sector dealing with other agencies of the Executive Branch recognized it as an acceptable substitute to the over 22 different policies that each organization needed to comply with in administering grants and contracts. This interest ultimately resulted in establishment of an ad hoc committee under the then Federal Council for Science and Technology in 1971 to study the possibility of a uniform patent policy that would satisfy the needs of all the agencies, the nonprofit sector and the public.

After four years of interagency meetings and innumerable drafts, the Federal Council for Science and Technology (FCST) endorsed the Committee's July 1975 report which recommended a modified HEW IPA program for discretionary use by all the R&D agencies of the Executive

(Attachment N). FCST further directed the Committee to implement its recommendations in the form of a Federal Procurement Regulation which is now in its final stages of clearance. Both the National Science Foundation and the Department of Commerce have implemented the modified HEW IPA since 1974. The 1975 report probably provides the most complete analysis available on why this program is the policy of choice in managing inventions resulting from Government-sponsored R&D grants and contracts to nonprofit organizations. While holders of IPA's retain the first option to retain title to inventions generated by grant-supported research, page 20 of the report sets out the major conditions which attach to executed IPA's:

> "A requirement for the prompt reporting of all inventions to the applicable agency along with an election of rights;
>
> "Reservation of all the rights specified in paragraphs (e)-(h) of the 1971 President's Statement on Government Patent Policy (the so-called 'march-in rights' for non-use and abuse).
>
> "A requirement that licensing by the universities will normally be nonexclusive except where the desired practical or commercial application has not been achieved or is not likely to be expeditiously achieved through such licensing;
>
> "A condition limiting any exclusive license to a period not substantially greater than necessary to provide the incentive for bringing the invention to the point of practical or commercial application and to permit the licensee to recoup its costs and a reasonable profit thereon;
>
> "A restriction that royalty charges be limited to what is reasonable under the circumstances or within the industry involved;

"A requirement that the university's royalty receipts after payment of administrative costs and incentive awards to inventors be utilized for educational or research purposes;

"A provision enabling the agency to except individual contracts or grants from the operation of the agreement where this is deemed in the public interest;

"A requirement for progress reports after designated periods and re-execution of the agreement only if the Government deems the university's performance to be satisfactory;

"A prohibition against assignment of inventions without Government approval to persons or organizations other than approved patent management organizations subject to the above conditions; and

"A provision permitting termination for convenience by either party upon thirty (30) days' written notice."

In addition to reinstating the Department's IPA program, in late 1967 through 1968 the Department began expediting its reviews for request for greater rights from nonprofit institutions and industrial concerns under 45 C.F.R. 8.2(b) and (d) and 8.6 in identified inventions made in performance of Department-sponsored grants and contracts. Since the reorganization of 1968 the Patent Branch has acted on between 30 and 40 such petitions a year, and presently has approximately 50 petitions in various stages of process. Each granted petition is subject to conditions similar to those attached to IPA's listed above.

Since 1969 through the Fall of 1974 the Patent Branch estimates that the intellectual property rights to 329 innovations either initially generated, enhanced or corroborated in performance of HEW-funded research were in the hands of institutions with IPA's or successful nonprofit

petitioners for the purpose of soliciting further industrial development support. The Patent Branch was advised that during the 1969-1974 period these universities had negotiated 44 nonexclusive and 78 exclusive licenses under patent applications filed on the 329 innovations. The Patent Branch estimates that the 122 licenses negotiated had generated commitments in the area of 75 million dollars of private risk capital. Since 1974 to the end of Fiscal Year 1976 the number of inventions held by universities has substantially increased to 517.

Attached are some examples of the inventions licensed by universities or nonprofit organizations which have reached or are near reaching the marketplace since our 1974 survey (Attachment O). Noteworthy is that this incomplete listing involves commitment of risk capital of approximately 80 million dollars. As will be noted, there are a number of pharmaceutical products on this list. No comparable situation was known at the time of the GAO Report of 1968. It should also be noted that over 60 percent of the rights retained by IPA holders or petitioners have not yet been licensed and may never be licensed and reach ultimate use. Accordingly, the mere retention of patent rights by an innovating organization is clearly not a guarantee of marketability.

In addition to initial administration of the IPA program and requests for greater rights discussed, the Patent Branch also acts as the management focal point for all innovations to which the Department retains title. The Department's patent portfolio consists of approximately

400 patents and patent applications which, as noted, are to a large extent HEW employee inventions. Virtually all of the 400 patents and patent applications require the filing of patent applications through the management facilities of the Patent Branch. A lesser number of the Department's patent portfolio are attributable to inventions made by employees of universities or commercial concerns funded by Department grant or contract which they did not choose to manage or were denied the right to manage. The Patent Branch adds approximately 30 to 40 patent applications to its portfolio every year at an expense of approximately $100,000.

Since 1969 we have granted 19 exclusive licenses and 90 non-exclusive licenses under our patent portfolio under 45 C.F.R. 6.3, which was amended in 1969 to provide for exclusive licensing when appropriate. The granting of such licenses is now also subject to procedures set out in the Federal Procurement Regulations on Licensing of Government-Owned Inventions. It should be noted that the 90 nonexclusive licenses do not cover 90 separate inventions, but cover a small number of inventions that have been licensed a number of times. For example, one Department invention on a diagnostic technique has been licensed approximately 22 times. The Patent staff, although making what we bleieve to be its best effort in licensing the Department's patent portfolio, has not been able to duplicate the effort of technology transfer evidenced by the university sector. (The Department is a major collaborator in NTIS's licensing program, which to date has been successful in licensing only DHEW's inventions.)

This appears to be attributable to at least the following factors: A loss of proximity and participation of non-Government inventors and/or innovating organizations, lack of staff, and onerous conditions and procedures of licensing required by the Federal Procurement Regulations on Licensing Government-Owned Inventions. While an increase in staff might enhance the possibility of licensing Government-owned employee inventions, such guarantee cannot be presumed to enhance the possibility of increased licensing of inventions made by non-Government inventors who have no incentive to participate. A basic tenet of successful technology transfer requires the presence and cooperation of the inventor and/or innovating organization as an advocate of its invention, or the possibility of licensing or transfer is severely decreased. The recent December 22, 1977 report on "Health Technology Management" does not respond to this axiom and appears to presume Department ownership of inventions in order to control their entrance into the marketplace. As noted, ownership of inventions made by non-Government inventors or innovating organizations severely impacts on the possibility of technology transfer due to the loss of the invention's advocate. Accordingly, this report is fatally flawed without explanation on how management can replace this loss of advocacy.

Little can be said about greater rights requests under 8.2(b) from commercial concerns, since the Department has had approximately 7 such requests to process since 1968. The lack of invention activity in either

the area of greater rights requests or invention reporting could be read as a deficiency in the quality of commercial contractors receiving research and development contracts from the Department where there are expectations of useful end items. Further, the contracting mechanism is no doubt being used to obtain R&D services to solve problems that will lead to useful end items through further but separate efforts. It is also possible but improbable that inventions are not being reported but are being maintained as trade secrets. This is deemed unlikely, as the Department has acted favorably on most requests for greater rights when accompanied by definitive development plans requiring investment of risk capital from commercial concerns making non-compliance with contract obligations unappealing and unnecessary.

IV. Analysis of Department Patent Policy and Possible Alternatives

Presuming that there is no need to discuss further allocation of rights to employee inventions in light of comments made above, present Department patent policy in regard to allocation of rights between the Department and grantees and contractors can be summarized as a mixture of:

1) Disposition of a first option to invention rights to nonprofit innovating organization at the time of grant under our Institutional Patent Agreement program and to commercial concerns under a small number of contracts entered into by the cancer chemotherapy research program, and

2) A deferred determination policy which entails allocation of rights after identification of an invention made by a grantee or contractor by an organization which does not hold either an IPA or is functioning under the cancer chemotherapy research program.

A. Alternatives to Department Policy

1) The policy recommended by Attorney General Rogers and the Justice Department requiring nonexclusive licensing or public dedication of the entire inventive product of Department R & D funding.

2) A policy deferring determination of rights to all inventions made by Department grantees or contractors until their identification. (This policy presumes the existence of an objective set of criteria which would enable consistent decisions in similar situations. The lack of such criteria or the program officials' failure to understand the criteria has in the past resulted in decisions based on an individual's particular political, moral or visceral reaction.)

3) A policy in which the Department takes title to all the inventions resulting from grantee or contractor R & D for the purpose of licensing either on a nonexclusive or exclusive basis, depending on the circumstances of the situation. (It should be noted that this alternative differs from (2) above, in that it eliminates the innovating organization from any licensing

function that will need to be undertaken. This policy also presumes the existence of an objective set of criteria to enable consistent decisions in similar situations.)

4) A policy extending the first option to invention rights of a modified IPA program to all grantees or contractors whether or not for profit.

5) A policy in which a Department research program is left to choose any of the above policies on the basis of their perceived mission and goal.

B. Discussion of Alternatives

Alternative 1.

First, it would appear appropriate to eliminate Alternative I as a realistic approach in light of this Department's past history in the early 1960's, which evidenced that there are few situations in which the Department funds inventions resulting from its programs to the point of practical application. Even assuming that we are dealing only in the "occasional situation" identifed by Attorney General Rogers, his suggested solution that the Government undertake to finance all remaining developmental and experimental work would require an extraordinary increase in the Department's R & D appropriation, especially in the area of drug development (and probably some medical devices), where economists indicate that the development and marketing of a single drug may involve an investment of between 12 to 24 million dollars. Even if such

development program were undertaken, it is unpredictable that if successful, a commercial concern would undertake the marketing of the end item without an exclusive market position, or at all, based on an assessment of a limited commercial market. Further, this option has been implicitly rejected by Federal agencies involved in R & D when required to use the uniform "title clause" of the Federal Procurement Regulations (41 C.F.R. 1-9.107-5(a)) as the clause requires the agency to entertain a request for greater rights from the innovating organization after an invention has been identified (Attachment P - see circled portion).

Last, the December 22, 1977 report "Health Technology Management" implies that patent rights should be utilized in certain situations to enhance the opportunity of technology transfer. This carries with it the suggestion of either Alternative 2 and 3 and eliminates Alternative 1, as "technology transfer" carries with it the need to create an exclusive position in some instances. (The report implicitly eliminates the IPA program and Alternative 4 without explanation, since the control envisioned by the report for "intervention" purposes requires continuous Department control over the innovation.)

Alternative 2:

The deferred determination policy of Alternative 2 can be viewed as possibly maximizing competition in the marketplace, since any grant of exclusive commercial rights will be made only on a showing

that exclusivity is the determining factor in bringing the invention to the marketplace. Inventions that could be marketed on a nonexclusive basis presume multiple sources of supply and competition. This alternative has much cosmetic, political appeal on the basis of producing the appearance of control over grants of exclusivity. Further, to the extent that it has been used as a portion of Department patent policy, it has not generated a great deal of adverse comment, especially since the term of exclusivity granted is normally much shorter than the full patent period. Notwithstanding, it is clear that a deferred determination policy extended to the entire inventive output of the Department's R & D program would have negative ramifications on the Department's ability to attract qualified contractors, the ability to assure utilization of the results of its research programs and would greatly increase the administrative burden on the part of the Government and its grantees and contractors.

More specifically,

a) The uncertainty of ownership involved in a deferred determination policy will discourage at least some commercial contractors from participating in Department programs. A commercial contractor whose privately financed background position would be jeopardized by a newly generated invention which he might not necessarily own must think seriously before taking a contract which intends to capitalize on his background

position. Refusal to participate in such a situation will probably necessitate that the Government contract with a less qualified contractor, or not contract it at all. This basically is the argument which the Department accepted in providing the first option to commercial contractors in the cancer chemotherapy research program, and why the drug development programs of NIDA and NICHHD have difficulty in attracting commercial contractors.

b) The long processing period inherent in a deferred determination policy would in some cases delay prompt utilization of Department inventions, since a participating contractor or grantee would wish to establish its rights prior to either investing risk capital or utilizing management efforts in seeking potential licensees. Utilization would also be adversely affected by the administrative burden of petitioning the Department for patent rights and the present Department requirement that the contractor or grantee file patent applications to protect the property rights during the petition period. Faced with these tasks, the participating contractor or grantee will have a disincentive to involve itself in inventions that appear economically marginal on first review.

c) For the Government to be right more often than not when making a deferred determination will require extensive technical, marketing, and economic studies of the firms, technology,

industries and market involved. The cost to taxpayers of such programs could be more than any savings they would produce for consumers. This appears to be the present situation, since on most deferred determination cases, exclusivity has been deemed necessary, and the costly determination process has been engaged in simply to confirm this fact. (Interagency statistics indicate that over 90 percent of all petitions are granted, and of those granted, fewer than 40 percent are licensed and a much smaller percentage commercialized - Annual Statistics on Government Patent Policy, Federal Council on Science and Technology.)

d) But most important, such a policy would eliminate the incentive in the nonprofit sector to establish a technology transfer function which has been the core of the growing success in extracting invention reports, filing patent applications and seeking and negotiating licenses now occurring within organizations in the Institutional Patent Agreement program. With no guarantee of ownership in the nonprofit organization, there is no incentive to perform these services. Under this alternative, rights in some cases will be lost due to the failure of the nonprofit organization to file patent applications within the statutory period initiated by publication due to a reluctance to commit funds prior to having its rights established. Elimination of the existing 72 IPA's and the technology transfer capabilities generated by their execution will predictably result in a severe adverse

political reaction prompted by the intellectual community that will be based on claims of excessive Department intervention and control of ideas that these organizations believe they have strong equities in, which the Department has not taken into consideration.

Alternative 3:

The Department ownership and licensing policy of Alternative 3 has all the positive attributes ascribed to Alternative 2. (As mentioned previously, the Department has a functioning licensing program that basically concentrates on Department employee inventions.) However, extension of this policy to the entire inventive output of the Department's R & D program has such severe negative implications that it approaches the point where it may be considered unrealistic when applied to other than Department employees. In addition to the serious problem of eliminating the 72 IPA's in existence, the following problems would also need to be addressed:

a) An extraordinary increase in patent staff and appropriations would be required in order to file patent applications on all the inventions previously managed by either IPA holders or petitioners under a deferred determination policy.

b) Notwithstanding an increased staff, the Department would have considerable difficulty in obtaining the services and cooperation of the non-Government employee and innovating organization in filing patent applications, negotiating licenses and rendering services needed by the Department and its licensee

in completing development and formulating marketing strategy. This is predictable due to lack of physical proximity and an incentive to involve inventors and their organizations in an endeavor in which there will be no reward. Further, lack of the ownership incentive may well result in inventors neglecting to make invention reports by merely placing inventions into the public domain through scientific journals. If this occurs, one must ask how the Department level function envisioned by the December 22, 1977 report on "Health Technology Management" will select the small number of high-priority technologies from the 36,000 scientific publications generated by DHEW annually?

c) The nonprofit sector will be deprived of an opportunity to develop through their own initiative ideas the Department decides do not evidence commercial value, since the Department will determine whether the filing of patent applications is appropriate. This will be viewed by some as a type of "thought control" or "book burning" on the basis that if patent licensing is ultimately determined to be necessary to assure utilization, a Department action not to file will suppress utilization. The December 22 report appears to intend this result.

d) Considerable delay will be involved, since it is unlikely that the Department will have the same flexibility in carrying out difficult negotiations now undertaken by the nonprofit sector.

e) There will be a need for increased legal staff in order to carry out time-consuming negotiations in exclusive licensing situations, since the terms of each negotiation will cary from invention to invention.

f) Since it is an axiom of "technology transfer" that a passive licensing program has little chance of success, since it relies on potential licensees to initiate contacts with the Department, the Department as licensor will need to appropriate funds to generate an active attempt to contact potential licensees through increased utilization of technology transfer experts.

Alternative 4:

While Alternatives 2 and 3 have a cosmetic appeal, Alternative 4 has the disadvantage of possibly being summarily dismissed in the political arena and by the Department of Justice without analysis, as being a "give-away," "anti-competitive," and providing to the contractor or grantee a "windfall." Initial discussion of the merits of this alternative are difficult to begin when one first must dispose of what is believed by operating personnel of the unworkable philosophy espoused by Attorney General Rogers and the Department of Justice for over 30 years. (The Rogers recommendation is merely a summation of the 1947 Attorney General's Report on Government Patent Policy, which was generated without the aid of operational data at a time when R & D funding was a small percentage of 1977's 26 billion dollar budget.) Analysis appears even more difficult when it must be admitted that there are only minimal government statistics that prove that the ultimate

marketers' financial contribution in bringing an invention resulting from Government funding to the marketplace is in any given case significant in comparison to that of the Government. However, the statistics that have been accumulated in this Department (see Attachment O) appear to indicate that inventions generated by the nonprofit sector with Department funding require a private risk investment for development purposes far in excess of that contributed by the Government in making the invention. In general, this alternative is thought to have the attributes of:

a) Maximizing the possibility of private development and utilization of Department funded inventions, since ownership of patent rights is a positive incentive for seeking investment and commercialization.

b) Minimizing the cost of administering patent policies, since uncertainty of ownership has been resolved at the time of grant or contract.

c) Attracting the best qualified commercial contractors, as a guarantee of ownership in future inventions assures that a contractor's background investment and innovations will not be endangered.

d) Recognizing the fundamental equities of grantees and contractors in their own inventions and the need for Government nonprofit organziations and industry to interact in a manner in which the particular capabilities of each will be utilized to their fullest extent.

Arguments that this alternative primarily enures to the benefit of "big business" appear to be greatly exaggerated and indicate a misunderstanding of the purpose of the patent system.

A strong argument can be made that allowing contractors and grantees to retain patent rights will tend to promote competition, whereas if the Department under Alternatives 2 or 3 adopts a policy of normally dedicating the invention to the public or licensing on a nonexclusive basis, concentration and monopoly will be enhanced. The proposition that title in the contractor or grantee can lead to concentration is very much dependent upon the assumption of a competitive marketplace in which all concerns start with equal capacities. In fact, many industries are currently oligarchial in structure and do not fit the model of pure competition. When this is the case, the retention of rights in the Government and a policy of nonexclusive dedication or licensing tends to serve the interests of the dominant firms for whom patent rights are not normally a factor in maintaining dominance. Rather, control of resources, extensive marketing and distribution systems, and superior financial resources are more important factors in maintaining dominance and preventing entry of new firms and ideas. It is important to note that dominant firms may well be foreign based and dominate due to subsidization by their governments, making the inadequacies of a policy of the Department normally licensing on a nonexclusive basis or dedicating even more pronounced. No one would agree that the Department should be conducting R & D and permitting the results to enure to the benefit of foreign governments willing to subsidize development

of ideas placed into the public domain by the Department to the detriment of our own economy.

On the other hand, smaller firms in an industry must by necessity rely on a proprietary position in new innovations and products in order to protect their investment in foreign and domestic markets. Thus, patent rights tend to be a much more significant factor affecting their investment decisions. They may need the exclusivity of patent rights to offset the probability that a successful innovation will lead to copying by a dominant firm which would soon undercut their position through marketing, financing, and other commercial techniques. Accordingly, if Alternatives 2 or 3 normally result in nonexclusive licensing or dedication, they may in fact be anti-competitive, since it encourages the status quo by discouraging promotion of innovations which displace old technology. Also, it is clear that the Department can determine with whom it wishes to contract and rule out contracts to firms it deems to be dominant.

Although not previously discussed but deemed of some importance is the fact that the Federal Procurement Regulations permit the use at the time of contracting of any patent clause that the Department deems appropriate in situations where the contractor substantially shares in the cost of the research. This section of the Federal Procurement Regulations has been utilized approximately four or five times in the last few years by leaving to a commercial contractor an option to future

invention rights in exchange for cost-sharing. It should be recognized that Alternative 4 could encompass the concept of cost-sharing as a condition to obtaining a first option when dealing with a commercial contractor. This mechanism could be a means of increasing the amount of Department contract research without increased appropriations.

Alternative 5:

A Department policy permitting research programs of the Department to choose what they believe to be the appropriate patent policy to achieve their mission would most likely result in the program manager's choice of options which best fit his particular political, moral or visceral reaction to the patent system. The likelihood of uniform handling of similar situations through the Department would be very slight and, accordingly, this alternative should be considered one with little merit. To a certain extent, this policy was in effect during the 1960's when NIH, the solid waste and air and water pollution programs (the three last programs now EPA) were administered by patent counsels that were virtually independent of central control and created in part the organizational problems discussed previously.

IV. Analysis of Present Department Policy

Inherent to the discussion above is a description and justification of the Department's present patent policy. A detailed analysis, justification and comparison to other possible alternatives to the Department's IPA program can be found in Attachment N. The most significant highlights of that report are as follows:

a) The nonprofit sector does not engage in the direct manufacture of commercial embodiments, and it is industry which must bring inventions made by the nonprofit sector to the marketplace.

b) Inventions arising out of nonprofit organizations' research are normally incidental to the research, and at most involve compositions of matter with no clear utility, prototype devices, or processes that have been tried only in the laboratory. It is rare for such organization to be in a position to bring an invention beyond the initial theoretical or laboratory stage.

c) The nonprofit sector without incentives created by other segments of society, including the Government, would not establish a technology transfer program capable of surfacing reportable inventions, filing patent applications and licensing industry when necessary to generate industrial risk capital to bring innovations to the marketplace.

d) Even in the situation where an industrial organization is able to overcome the "not-invented-here" syndrome (disinterest in ideas emerging from other than a concern's own research), experience indicates that a collaboration with the nonprofit organization in order to bring its inventions beyond the theoretical or laboratory stage may require a guarantee of some patent protection to the industrial collaborator.

In light of these factors, it was deemed necessary that the Department create an atmosphere conducive to the transfer of inventive results from the nonprofit sector to industry. It appeared essential that the Department induce the nonprofit organization to provide an internal mechanism that would serve as a focal point for receipt of inventive results of its research for later disclosure to those industrial concerns most likely to utilize such results. In order to encourage forming a technology transfer mechanism in the nonprofit organization, it was believed necessary as a first step to permit qualified organizations to retain the principal rights to Department supported research. Retention of such rights carried with it the right to license commercial concerns and create the motivation necessary to induce the nonprofit organization to seek industrial development of its inventions and overcome the industry attitude to rely only on ideas emerging from in-house research (the not-invented-here syndrome).

Other benefits that flow from the university IPA are the ability to recognize the equities of other co-sponsors of its research due to the organization's ownership and the ability to utilize royalty return for additional research at such organization.

The pro's and con's of the deferred determination policy have been discussed elsewhere in the report and require little additional comment.