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Call Hirschmann and get report and comments

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

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.

HISTORICAL EVOLUTION OF DEPARTMENT PATENT POLICY AND PRACTICE

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 (Reor. Plan No. 1 of 1953). The patent regulations of the Federal Security Agency (Attachment A) served as the model for the existing Department's regulations (45 C.F.R. Parts 6-8) (Attachment B). 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 ~~the~~ 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 C). 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.

The 1962-1968 Period.

In 1962 the first suggestions 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 D) 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 nonexclusive 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.

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 E) 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 F). 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 read to be consistent 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," 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, 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 G). 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 long period of uncertainty over allocation of inventions resulting from Department-funded grants and contracts was brought to a close by the GAO report B-164031(2) of August 12, 1968, "Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry" (Attachment H). 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 response to this criticism, James F. Kelly, Assistant Secretary, Comptroller, DHEW, indicated by letter of March 20, 1968 (copy in rear of Attachment G) 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.

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 I). 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 strived 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 re-examination 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. In that regard both the Association of American Universities in response to Secretary Califano's "Operation Common Sense" (Attachment J) and the Commission on Federal Paperwork (Attachment K) 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 (Attachment J).

With the reorganization of 1968 accomplished, the Department acted to terminate the 17 IPA's in existence since 1955 and substitute

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.

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 L). 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. Page 20 of ~~this~~ report sets out ~~the general terms~~ which ~~should be~~ attached ~~to~~ ~~IPA~~ ~~deemed appropriate~~.

"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;

"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) 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 DHEW-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 ~~understands~~ 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 M). 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.

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. Since 1969 we have granted 19 exclusive licenses and 90 nonexclusive 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 believe 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. This appears to be attributable to at least the following factors: A loss of proximity to non-Government inventors, lack of staff, and the onerous conditions and procedures of licensing required by the Federal Procurement Regulations on licensing Government-owned inventions. While an increase in staff may 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. In other words, experience indicates that without the presence and cooperation of the inventor as an advocate of his invention the possibilities of licensing for technology transfer of such inventions is severely decreased.

Little can be said about greater rights requests under 8.2(b) from commercial concerns, since the Department has had fewer than 10 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 serious deficiency in the quality of contractors

receiving research and development contracts from the Department where there are expectations of useful end items. ~~However~~, the lack of activity in this area could be explained by a ~~lack of~~ imaginative proposals from industrial concerns, ~~or use of~~ the contracting mechanism to obtain R&D services to solve problems that will lead to useful end items through further but separate efforts.