

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

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 <sup>perceived</sup> 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

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*Some massive*  
*ideas missing*  
*ambition, will balance*  
*incentive to use*  
*great resources*

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*at an*  
*Xerox*

*G.E., IBM, Am. Tel.*  
*Del., G.M., et*

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.

*unclear*

### 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

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.

What should be done about this? Needs explanation + Comm.

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 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. (The Department is a major collaborator in NTIS's licensing program, which to date has been successful in licensing only DHEW's inventions.)

*in what place?*

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

too strong

it isn't a good report  
but this is not the fatal flaw

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

*Unnecessary  
Comment*

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 <sup>for anti-tumor drug development</sup> ~~the cancer chemotherapy research program~~, and <sup>Division of Cancer Treatment, NCI</sup>

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 <sup>anti-tumor drug development</sup> ~~cancer chemotherapy~~ <sup>program of the NCI</sup> ~~therapy 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



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.

*Inventions  
are made a  
small part  
of the  
total  
output.*

*delete*

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:

*belong  
up  
front!*