BACKGROUND PAPER
TO
SUPPORT AND EXPLAIN THE NEED FOR THE PROPOSED
"UNIVERSITY AND SMALL BUSINESS RESEARCH
UTILIZATION ACT OF 1976"

Introduction

The University and small business communities are jointly seeking Congressional support for legislation to improve current Government policies as they affect the allocation of rights to inventions made by these organizations under Government grants and contracts.

The proposed Act represents an attempt to seek a solution to specific problems that face both of these groups, but does not try to arrive at an overall solution to the Government patent policy issue. In the past almost all bills proposed in this area have been broad in scope and have dealt with the whole range of Government R & D contractors and grantees. The result has been that the interests and needs of the university and small business communities (which collectively perform at least 36% of all Government-sponsored, extramural R & D) have been lost in heated argument and debate over the treatment of large, industrial contractors. As will be discussed in more detail, it is becoming increasingly evident that the interests of these two groups were not understood by the framers of Section 9 of the Federal Nonnuclear Energy R & D Act of 1974 which has become the model for subsequent legislation. Other recent administrative developments do not portend well for the future. Hence, the proposed bill represents a viable and responsible approach to Government patent policy that will satisfy the needs of these two groups and at the same time promote and protect the wider public interest.

The Goals of the University and Small Business Communities

The proposed Act is designed to achieve a number of goals of the small business and university communities. Most, if not all, of these goals coincide with wider national goals such as increasing competition, economic growth, and job expansion.

The university community seeks a Government patent policy that will have the following characteristics:

(1) A simple and uniform system that minimizes administrative burdens on the university community (and coincidentally the Government.)

(2) A system that provides at least the minimum incentives and conditions necessary to achieve to the maximum extent practicable the commercialization of university inventions made under Government awards.

(3) A system that will encourage industrial sponsorship of university research.

(4) A system that will recognize the equities of the universities, other university sponsors, and, in many cases, the States which support the universities.

The small business community also seeks a system that is simpler and less burdensome and which recognizes their equities. However, small business is especially concerned that Government patent policy-

(1) make it attractive for small business to participate in Government sponsored research and allow small business to more effectively compete with larger competitors for Government support, and

(2) allow small business to use inventions made by them with Government support to maximize firm growth and enhance their competitive positions in non-government markets.

The Act proposed will accomplish these goals while at the same time promoting larger national goals of increased competition, increased innovation and product development, and increased economic growth and job expansion. At the same time the Act would protect the Government's interests by providing it with a royalty-free license. It also would allow the Government to make exceptions in certain classes of cases or on a case-by-case basis. And the right of the Government to require licensing in

cases when small business firms or universities fail to take effective steps to develop inventions is a feature of the proposed Act.

The Current Situation and Policies

At the outset, it must be understood that the current situation is generally counterproductive to these goals, and, if anything, seems to be moving in an even more counterproductive fashion.

As identified in section 11 of the proposed Act, there are currently 19 different statutes governing different Government agencies or programs. Sometimes different programs within the same agency will be governed by different statutes, or some programs of a given agency may be governed by statute and others not. These statutes tend, with a few exceptions, to encourage retention of title to inventions in the Government, but normally allow agencies flexibility to grant waivers.

In addition to these statutes, most agencies have shaped their policies around the Presidential Memorandum and Statement of Government Patent Policy issued in 1963 by President Kennedy. However, this Statement is so structured to accomodate a myriad of practices and leaves considerable operational flexibility in the individual agencies.

The result of the above is that there are at least as many different patent policies and procedures as there are agencies. Agency clauses tend to differ. Willingness and procedures for negotiating clauses and after the fact waivers vary considerably from agency to agency, and even sometimes within different elements of the same agency. Similarly, the terms upon which waivers are granted tend to vary considerably. For universities and small business firms that deal with several agencies, it becomes an enormous burden just to understand the differing requirements and procedures imposed by these agencies.

However, while the details and specific procedures tend to differ considerably, the broad outlines and net result are often the same. Universities can expect their Government awards to include terms allowing the Government to take title, but allowing deferred determinations of rights after inventions are identified. The only current exceptions to this are DHEW and MSF which have entered into Institutional Patent Agreements with some universities which give them a first option to retain title. Up until a few years ago DOD gave favorable treatment to universities on a list of institutions with approved patent policies. However, this was discontinued when, the Armed Services Procurement Regulations were conformed to the Federal Procurement Regulations, and it is not clear what DOD's present intentions are. Small business firms can also normally expect to receive a title-in-the-Government or deferred determination clause from all agencies except DOD. Usually, they would have to negotiate on a case-by-case basis for more favorable treatment.

Moreover, the ability of agencies to grant more favorable treatment as a result of negotiations, or under deferred determinations, or through IPAs is increasingly being placed under legislatively created burdens and procedures. For example, Section 9 of the Federal Nonnuclear Energy R & D Act of 1974 places a presumption in favor of title in the Government, and though it does allow DOE the flexibility to grant waivers it requires the consideration of a rather extensive list of factors prior to such grants. This Act has been interpreted by DOE as preventing it from using an Institutional Patent Agreement approach with respect to universities, thus making it more restrictive than the President's Policy Statement. It also plays mere lip service to the needs of small business firms and essentially requires their compliance with the same expensive and time consuming procedures with which larger and more financially able competitors are faced. Unfortunately, section 9 has since been incorporated by reference and made applicable to three more Government R & D programs. It appears to be the waive of the future.

Recent developments on the administrative front also point to a movement in Government patent policy more in the direction of a title-in-the-Government approach regardless of the type of performer involved. The primary example of this was the recent decision of OMB/OFPP to suspend recently issued amendments to the Federal Procurement Regulations which for the first time formally recognized and authorized the use of Institutional Patent Agreements for university contracts. These regulations had been widely supported and commented upon in draft form by the university community and others in 1976. They implemented recommendations in a report on Government patent policy vis-a-vis universities that was approved unanimously by the FCST Committee on Government Patent Policy in 1975.

Equally disturbing are recent developments within DHEW which currently funds approximately one-half of all Federally-supported, university research. It is understood that waiver petitions from institutions and contractors not holding IPAs are all now being held up within DHEW. It is also understood that a paper is being discussed internally within DHEW which seriously proposes the abolition of IPAs. Thus DHEW may be headed back to its regressive policies of the early 1960's which were sounding criticized by the General Accounting Office in 1968. The current policy follows suggestions of the GAO.

Furthermore, it is our understanding that President Carter has indicated a predelection towards use of a title-in-the Government approach. Why he has done so we do not know, but it seems to stem from his association with Admiral Rickover who, contrary to almost everyone else in DOD, has been a long time advocate of a title-in-the-Government approach for all Government contractors be they large or small, profit or nonprofit.

In view of all these trends, both legislative and administrative, the university and small business communities consider it imperative that legislation extracting them from the

deeping morass of Government patent policy be enacted lest their positions become completed eroded.

The Proposed Act's Treatment of Universities and Nonprofit Organizatio

The proposed Act is designed to overcome the current problems and to achieve the goals of the university community by normally allowing universities and nonprofit organizations the right to elect to retain title to inventions made by them with Government support, subject to various requirements and safeguards substantially similar to those now included in the Institutional Patent Agreements awarded by DHEW and NSF.

(1) Commercialization of University Inventions

This mix of rights and obligations represents the minimum but critical rights necessary to obtain the commercialization of inventions made by universities. In order to understand why this is so, one must understand the nature of university research, the inventions that flow therefrom, and the factors that affect the transfer of these inventions to the commercial marketplace.

The Federal government sponsors research in universities to expand the boundaries of existing knowledge in areas or on problems deemed to be in the public interest or to be related to national goals. Universities are usually (unless they are doing classified research) free to publish research results which are generally made available to all. The right to publish is normally preserved in the negotiation of grants and contracts, as is the sponsoring agency's right to receive agreed upon reports.

The generation of inventions is almost never the main objective of the research conducted with federal funds; rather, an invention generally is an incidental "byproduct" of the research activity, largely attributable to serendipity and/or the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university.

Moreover, these inventions, unlike those of larger industrial firms, normally stand alone. As explained in a Harbridge House study:

> "Their isolation is a major obstacle to utilization since most inventions are not marketable products in themselves. The industrial product is often protected by a cordon of patents, as illustrated by the list of patents on a packet of Polaroid film. A university invention, on the other hand, is a one-shot patent. Even if the patent specification discloses an ingenious invention, the patent claims which define the scope of monopoly are likely to be narrowly drawn. Whereas industry will add to its patent arsenal as a product is improved, a university patent, if it is to be licensed at all, must be licensed on the initial effort."[1]

Education institutions are, of course, not organized either to manufacture or to produce and market patentable inventions. Neither, for that matter, is the Federal government. Accordingly, if university inventions are to be used, such institutions must seek to interest those in the industrial world who have the commercial capability for invention development and also, very importantly, market development, which the university lacks. This is often a difficult task, since few inventions coming out of university research offer readily recognizable prospects of a large market or a high return on investment. Moreover, the "not-invented-here" syndrome often poses a difficult institutional barrier. University inventions, since they most often correlate with the results of fundamental research, tend to be, at best, in the early stages of development, and therefore require the investment of substantial private risk capital to develop the invention to the appropriate state for introduction into the market.

At the same time, universities are in a unique position to objectively seek the best qualified industrial developer and under appropriate licensing arrangements monitor the diligence of development efforts by such a developer. If universities cannot

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[1] Harbridge House, Inc., Legal Incentives and Barriers to Utilizing Technological Innovation, pp. 11-13 (March 1974).

furnish, if appropriate, an exclusive license to developers for a limited period and thereby secure the investment of necessary capital, inventions resulting from government awards are less likely to be developed to the point of marketability, and thus the public is less likely to receive the benefits from such inventions, or at least may not receive them as quickly as otherwise would be the case. Moreover, most universities, though they rarely make any sizeable income from inventions, would largely lose all incentive to seek licensees if they did not hold patent rights. Because of the "publish or perish" ethic and the wide availability of the results of Government supported research, the university normally neither could nor would consider it appropriate to deal in "trade secrets."

When the right to seek patents resides in universities, appropriate patent applications can be filed promptly and negotiations immediately commenced with prospective developer/licensees, with the active assistance of the inventor. When this right does not exist at the time of contracting, but must await a determination after the invention has been identified, substantial time is usually required to prepare the necessary documentation for the sponsoring agency and for the agency to make a determination. While awaiting the outcome of such administrative process, the invention lies dormant, with the attendant risks that the inventor's interest in assisting in the development becomes attenuated and that intervening events may foreclose successful transfer of the invention to the public. For example, a potential licensee may decide to put his efforts elsewhere rather than wait for a decision.

Since deadlines for domestic and foreign patent applications are affected by publication of patentable ideas in scientific journals or thesis papers, delays in determining the disposition of rights to an invention can result either in delay of publication of research results or, what is more normally the case, the expiration of the time limit in which patent applications can be filed. Neither choice benefits the public.

generated inventions under a system which offers adequate inducement to those who can bring the fruits of the research into a form useful to the consuming public. Mere exclusivity in patent rights does not ipso facto create artifically high prices for related products and royalties generally represent only a very small fraction of the retail price of marketed goods. Moreover, one must face the inescapable conclusion that the development of inventions under a reasonable Government patent policy will benefit the public by making available products that would otherwise not have been available at any price and which are presumably more attractive to the purchaser than other alternatives or substitutes.

Without exclusivity to some degree, private sources are unlikely to have sufficient incentive to invest in the effort necessary to develop most university inventions. Indeed, the investment required to bring a product or process to a marketable condition and to introduce it into the market is almost always far greater that the investment in the original research from which the invention resulted.

To bring an invention to public use, further development or engineering is required, such as testing or "screening" of new chemical compounds. Before the efforts and expenses incident to testing or screening are undertaken, investors need to know who has the title to or ownership of the invention (i.e. the right secured to inventors and their assignees or licensees, for limited times, as authorized in the Constitution.)

Often prospective licensees will refuse to undertake the testing, screening, or development of inventions unless the licensor can grant an exclusive license for commercial use or sale. In some cases, no viable alternative has been available and, in the absence of an exclusive license, the use of the invention has been denied to the public. Indeed in the case of pharmaceuticals this has

been well developed in the 1968 GAO report mentioned above and by subsequent comparisons of investment in HIH supported, university inventions ante and post 1968.

Universities usually do not possess the resources, critical facilities, or controls necessary to bring drug products, for example, through the clinical testing stages to marketability. Thus, it is imperative that they be in a position to supply an incentive under appropriate licensing arrangements to those organizations which have those facilities and control capabilities.

Since Government personnel would not be as intimately familiar with an invention as those that have made it at a university, they would be in a much less favorable position to ascertain or pursue the commercial marketability of such an invention, and it is feared that the time that would have to be invented in such activity could well cause a significant reduction in invention disclosures from university researchers, with a consequent reduction to public access to potential research applications.

Thus, the primary result of the economic stimuli afforded by a realistic patent policy is the introduction and production of new goods or services into the economy. The influx of new technology and products should stimulate competition and economic growth.

(2) University/Industrial Collaboration

The University community also believes that a Government patent policy such as that proposed in the Act is needed to foster greater industrial sponsorship of University research.

In FY 1976 of a total of $3.724 billion spent on R & D at universities around two-thirds or $2.501 billion came from the Federal government. Of the remainder only $123 million came from industrial sources with the other $1.1 billion coming from institutional funds, state and local governments, and other nonprofit institutions such as foundations. The university community believes that there exists a real potential to increase industrial support

for university research. At the same time it is apparent that to exploit this potential more favorable Government patent policies must be developed. Because such a high percentage of university investigators receive Federal support under conditions allowing the Government to obtain principal rights in any inventions, many firms that might otherwise be interested in supporting or collaborating with university scientists are reluctant to do so. They fear that the results of work they sponsor may become entangled with Government claims under its work such as to jeopardize any exclusivity they might gain.

The proposed Act would largely eliminate this problem. The benefit to the universities and nonprofit section should be obvious. At the same time, increased industrial sponsorship might ease the burden on State governments and would also have the tendancy of decreasing the absolute amount of Federal support required and/or decreasing overhead and other indirect costs paid by the Federal government by widening the base of university sponsorship.

(3) Uniformity

The proposed Act would eliminate the extensive burdens of the current deferred determination approach. Moreover, the adopting of a single, standard clause will eliminate unnecessary administrative differences.

(4) Recognition of Equities

Finally, when patentable inventions occur, the equities to be considered include not only those of the Federal government, but also those of the inventor, the university, and, occasionally, other sponsors. Rarely are federal funds the sole factor contributing to the making of an invention. Beyond the critical contribution of the investigator, the university itself virtually always helps to finance the laboratories, equipment, and personnel contributing to an invention. It also provides a scholarly atmosphere, and sometimes the infusion of funds obtained from nongovernment sources. Each of the parties has a claim in equity.

A policy which assigns patent rights to the Government for all federally supported research eliminates the equities of all parties but the Government. The proposed Act overcomes this by allowing the equities of the university, the inventor (through royalty-sharing), and other sponsors to recognized. At the same time, the Government's interest is protected by a royalty-free license to practice any inventions for Governmental purposes. Beyond this, since the taking of title by the Government would tend to inhibit commercialization, it is difficult to understand what other need the Government has for any greater rights (other than "march-in" rights and other such safeguards included in the Act.) The proposed act also provides that the Government will receive its investment back in those cases when a university earns substantial income from an invention.

The Proposed Act's Treatment of Small Business

As with universities, the proposed Act would normally allow small business firms to retain rights in any inventions made under Government contracts and subcontracts, subject to various conditions.

(1) Improving the Competitive Position of Small Business Firms

For reasons closely related to those discussed in the previous section, small business concerns often require the retention of patent rights in their inventions in order to attract investment capital or to otherwise make risk taking a reasonable proposition. It ought to be obvious that if the Government takes title to inventions made by small business firms it is, in effect, removing the incentive for those firms to develop the inventions. That is, when a large company makes an invention it may be better able to develop it without patent rights because it enjoys other advantages such as financial resources, economics of scale, access to resources, and well developed marketing and distribution systems. On the other

hand, most small firms must place much greater reliance on patent protection to prevent larger competitors from undercutting new products and markets which they may develop. The result of a title-in-the-Government approach vis-a-vis small business firms is thus to favor larger, more dominant firms, either foreign or domestic.

Since almost all the arguments of those who advocate a title-in-the-Government approach are based on the conjecture that leaving title in large contractors will be anticompetitive, we fail to understand why these arguments should be extended to small business firms.

We believe that the proposed bill leaves sufficient safeguards in the Government either at the time of contracting or after a contractor has elected rights to ensure that the goals of the Act are met with due recognition of unusual circumstances. We also believe that the benefits that will accrue to small business firms will translate directly into greater economic growth and job expansion.

Although we believe the relationship between innovation and new product development and long-term economic growth and job expansion are intuitively and historically obvious, several recent studies are cited below to illustrate this. They stress the importance of a healthy small business enterprise to these goals.

A 1967 Department of Commerce study 1/ and a more recent update of that study by John Flender and Richard Morse of the MIT Development Foundation, Inc. 2/ lend strong support to the proposition that sales growth and job creation occurs more rapidly in innovative companies than in mature (dominant) companies. And even more significant for purposes of this analysis is the fact that job expansion

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1/ Technological Innovation: Its Environment and Management, U. S. Panel on Invention and Innovation. (Washington, D. C., GPO, 1967).

2/ John O. Flender and Richard S. Morse, The Role of New Technical Enterprises in the U. S. Economy, M.I.T. Development Foundation, Inc., October 1, 1975.

at young (i.e. small) high technology companies was even more spectacular. 3/ These findings indicate that a patent policy that would deemphasize the needs of smaller firms and emphasize concerns with larger firms could have a negative impact on job expansion.

The potential harm that could accrue from discounting the need to be concerned with inventions from nondominant firms is further emphasized by a study done by Gelman Research Associates. An international panel of experts selected the 500 major innovations that were introduced into the market during 1953-73 in the U. S., U. K., Japan, West Germany, France, or Canada. Of the 319 innovations produced by U. S. industries, 24% were produced by companies with less than 100 employees. Another 24% were introduced by companies with 100 to 999 employees.

(2) The Ability of Small Business to Compete For Government R & D

As previously noted current patent policies of all agencies except DOD generally require all potential profit-making contractors, be they big or small, to accept a title-in-the-Government or deferred determination type patent cluase or to engage in negotiations on this point. The effect of this is to actually place smaller firms at a relative disadvantage to larger firms. The situation might be analogized to the old saw about the law imposing the same penalty for sleeping under the bridge be the offender rich or poor.

Put simply, current policies often place a high-technology, small business firm in the position of acception Government dollars at the cost of jeopardizing its future non-Government market position. While the same could be said of larger firms, it must be remembered that for them patents do not usually play as important a role in the maintenance or expansion of their markets. Moreover, larger firms may be in a much better financial position to resist

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3/ The authors found that during the 5 year period of 1969-74 "six mature companies with combined sales of $36 billion in 1974 experienced a net gain of only 25,000 jobs, whereas the five young, high technology companies with combined sales of only $857 million had a net increase in employment of 35,000 jobs.

Government demands and negotiate more equitable patent provisions. And they will normally have more resources to allocate to contract negotiations or after-the-fact waiver petitions. Furthermore, larger companies are better able to segregate Government and non-Government work in separate divisions so as to guard against their commercial lines being jeopardized by Government claims under R & D contracts.

For these reasons, we believe that a patent policy along the lines of the proposed Act will have an appreciable impact on the ability of the small business community to compete for Government support. At a minimum it will end the unfortunate dilemma of choosing between one's corporate "birthright" and a "mess of Government porridge."