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INTRODUCTION

A new institutional patent agreement has been published by the GSA and is presently in a "hold status" until July. Questions have been raised regarding the basic policies which underlie the IPA. This paper is meant to respond to specific questions raised by Senator Nelson in regard to those policies.

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The question of whether Universities should retain patent rights arising from their research and the question of whether independent Government contractors should retain rights to patents arising from their work are two separate and entirely unrelated issues. University research produces inventions which are embryonic, invariably requiring significant amounts of risk capital to bring them from their basic research status to a state of marketability. In contrast, contractor inventions are, when they have applicability to the commercial marketplace, generally finished products requiring substantially less risk capital to bring to market. Contractors' inventions will therefore be marketed with or without the patent rights. University inventions will not see the marketplace unless patent rights are available to protect the provider of risk capital. Furthermore unless the University retains patent rights, it has neither the means nor incentive to undertake an active role in transferring its technology to industry.

The new IPA has no constraints upon the "type" of patent management organization (PMO) to be utilized by the University. However, this is in consonance with the present National Science Foundation's IPA.

To operate a PMO, whether it be "not for profit," "for profit," or internal to the University, requires substantial investments of risk capital. Independent PMOs provide service to the University community which cannot be duplicated by the individual Universities themselves. Obviously, Universities, in choosing a PMO, are intent on picking one with the requisite skills, reputation and assets to carry out a program which will provide the best service to the University.

RESPONSE TO QUESTION 1

1. How do Universities differ from industry when considering the disposition of the results of Government funded research?

Universities are nonprofit organizations which exist for the benefit of man to educate and to expand man's store of knowledge. When a University solicits a Government grant or contract, it has no profit motive. Usually the type of research which is supported is, by its very nature, oriented toward basic or pioneer efforts in a particular field. If an invention occurs, it is usually far from a commercial reality and fortuitous. It is the practical result of a fundamental inquiry not initiated because of its potential commercial merit.

On the other hand, industry's reason for existence is to make a profit for its stockholders. When industry solicits Government research contracts, it does so for the purpose of making a profit. Such contracts most often lead to the development of finished products which, if they have commercial potential, are very nearly ready for the marketplace. Patent rights left with the contractor, thereby give an immediate return to him in the form of a monopoly on a product for which the Government has often paid the entire development cost. The results of University research, being embryonic in nature, must be further developed with private funds if they are to arrive at the marketplace. Patent rights are the University's bargaining tool which enables the University to interest a company in furthering the development of the University invention.

Without patent rights, there is very serious question as to whether most University inventions will ever see the commercial marketplace. Private funds will be directed elsewhere where the potential for a return is real. By contrast, since the contractors' product is already developed at the end of the contract, all of the venture capital necessary to bring that product to the marketplace has been provided by the Government and the presence or lack of patent rights will have little if any effect on the decision of the contractor as to whether it will or will not market the product.

Finally, the industrial contract investigator may have a vested interest in retaining valuable resultant technology, event though the company may not be the best candidate to exploit the work. The University on the other hand has no vested interest. Its sole concern is to seek the best industrial partner to bring the work to the marketplace. Industry may bury a development; a University has an incentive to transfer technology, not only for the economic reasons described above, but also to fulfill its role as a humanistic resource.

2. Why did GSA eliminate the restriction "not for profit patent management organizations" from the Department of Health, Education and Welfare Institutional Patent Agreement? To make DHEW consistent in policy with other Government funding agencies which have no such restriction, and to expand the technology transfer industry.

There are four pathways for the transfer of University generated, Government funded technologies:

(a) Each University can create an "in-house" patent management organization. This is rarely satisfactory. "In-house" capability demands creation of a structure which is uneconomical in allocation of resources: there are required campus interviewers in a multiplicity of disciplines, patent attorneys expert in different specialties, licensing personnel with knowledge of many diverse industries. Few Universities can afford to do anything like an adequate job.

(b) "Not for Profit" patent management organizations. Research Corporation is the only sizeable organization in this class. It cannot begin to service the entire University community. Research Corporation operates in a passive mode; because of its many contracts, it cannot generally reach into the Universities for disclosures, responds only to inventions submitted to it, and accepts less than three percent of submissions made.

(c) Government could transfer University generated technology. To date, NASA (for itself) and the National Technology Information Service (Department of Commerce) act to transfer such technologies as are submitted to it from various agencies: DOD, DOE, DHEW and NSF, among others. This capability could be extended to funded University inventions. However, neither NASA nor NTI have been particularly successful in their activities. Again, their mode of operation is passive: they list and disseminate information about inventions which is sent to them. Alternatively, Government could set up an "active" technology transfer capability.

(d) It became apparent in 1974, when Government demanded that Universities establish technology transfer capability in order to obtain funding, that neither "in-house" nor "not for profit" mechanisms were adequate to do the job for most institutions. Government was not, and is not, in the field. "For profit" patent management organizations came forward, and one reason for GSA's change in the

DHEW IPA is undoubtedly to recognize and encourage their entry into the field. There are three principal PMOs "for profit" serving the University community: A. D. Little Co.; Battelle Development Corp. and University Patents, Inc. Each has multidisciplinary capability, has been carefully screened by its client Universities, and has met with the approval of DHEW and NSF as capable and reputable.

It should be noted that neither President Kennedy's nor President Nixon's policy statements on technology transfer restricted the funding agencies to approval of "not for profit" PMOs only. Department of Defense, NSF and other agencies do not so limit. The DHEW restriction was self-imposed. The G.S.A. change may have been made to bring DHEW into phase with other funding agencies.

3. How is technology transferred? What are its problems? Why are PMOs needed?

Technology transfer has four main compartments:

- (a) Identification;
- (b) Evaluation;
- (c) Protection; and
- (d) Licensing.

(a) Identification of an invention demands professional patent capability. University faculty researchers are accustomed to considering their efforts as a continuum: "idea/theory/experimentation/refinement/publication." They are not trained to recognize the point in the chain at which, legally, an invention has occurred. They may have done everything but make the legal invention; they may make an invention and not know it. And if they know they have made it, they may not recognize that it has usefulness beyond being an intellectual curiosity. Or, recognizing the invention, they may believe society will best and most quickly benefit from its dissemination by publication.

Identification requires a one-on-one meeting between the researcher and an interviewer with substantial knowledge of the researcher's discipline and of patent law. Patent lawyers today are almost as specialized as physicians. IPAs require the Universities report inventions made under funded sponsorship. Expertise of PMO interviewers at the essential identification stage have characterized many "ideas" as "Inventions" and caused their entry into the reporting pipeline.

- (b) Evaluation subdivides into three groupings:
- (1) technical feasibility;
 - (2) patentability; and
 - (3) commercial potential.

1. Technical Feasibility. Will it work? University generated technologies are most often at an embryonic stage of development. The PMO may use its in-house expertise to assess feasibility. Because disciplines are so varied, it must have access to a network of consultants--some on its payroll, some at its client Universities, some among its industrial contacts. All take disclosure under carefully prescribed legal agreements to prevent any inference of wrongdoing, and to protect the invention from inadvertent publication and concurrent loss of foreign patent filing rights. This is peer review; quick, tough and realistic.

2. Patentability. Can the invention be protected? Professionals knowledgeable in the law and in the technology must search for prior patent art, must search the literature, must distinguish the current invention from what may have gone before it. At this stage, extensive communication with the inventor often takes place as he and the professional define, refine and frequently expand the invention. Protection must be expectable which will not be easily circumvented or "designed around," lesser protection is no protection.

3. Commercial Potential. Will it sell? The PMO must undertake the positive activity of determining if the invention is deserving of transfer. Industry must be probed, but confidentiality is required and must be negotiated, particularly if patent protection has not yet been sought.

What has the PMO spent, so far, in identification and evaluation? For identification, there is no way to know on a per invention basis. But any major institution demands thirty to fifty professional man days on campus per year at a cost of \$300.00 to \$350.00 per day for salary and expenses. Disclosures of substance, which are perhaps three out of five, will require ten or more hours of professional time at \$75.00 per hour.

(c) Protection. Having identified and evaluated an invention, and decided it merited protection, the PMO must now commit sizeable risk dollars. Since University inventors are anxious to publish their results and often do not disclose until manuscripts are already submitted, the evaluation is often abbreviated, the decision premature and the risk is exaggerated. A patent attorney must be assigned to preparing the case in conjunction with the inventor. To retain the right to file for foreign patents, a U. S. application must be filed before the publication appears, then there is one year available from the date of the U. S. application to file in most principal countries. If publication precedes the U. S. application, the PMO has one year

from publication to file domestically. A domestic search will cost about \$200.00; U. S. patent applications will average \$1,500.00. If worthy of foreign filing, at least four or five countries are included at an average cost of \$1,000.00 each. To prosecute the U. S. case to issue will cost about \$1,000.00 more, and each foreign case will cost \$1,000.00 for prosecution, and issue fee. An average foreign patent which issues will cost \$100.00 per year per country for its life (10 to 15 years) to be maintained as active.

A filing decision is a commitment of about \$2,500.00 domestically, and \$1,000.00 to \$2,000.00 for each foreign country. This is risk money. The PMO never knows if the patent will issue, and does not know if the issued patent will, in fact, be licensed.

(d) Licensing. Once protection has been established by a patent application, the PMO must begin the transfer function. Logical industrial candidates must be identified. They must be approached by mail, by telephone, by personal meetings. The technology must be presented, explained, defined and defended. Negotiations for funding and licensing must be undertaken.

Transferring University technology is difficult because University inventions are rarely "near to market." Especially in the life sciences, where Food & Drug Administration and EPA requirements are stringent and their fulfillment time consuming and expensive, industry can accept a very limited number of candidates each year for exploitation. University inventions must compete with "in house" developments which always enjoy a preference in the scramble for available funds.

Although exceptions will occur, the process from initial presentation to ultimate license may take from one to three years. For that minority of inventions which are licensed, receipts of revenue in excess of pro forma amounts may take from two to six or seven years from the date of licensing. During these periods, the University may receive research funding from the licensee; but the PMO will receive only a share of the "front end" payment, if it was able to obtain such consideration. For any further remuneration, it must await royalty-bearing transactions.

Technology transfer requires the capabilities of a patent management organization. University "in-house" PMOs are not economically viable; "Not for Profit" has only one significant practitioner, and is not likely to be duplicated.

Government can, if it chooses, create an active PMO structure. A new agency will be required, to be staffed and continuously motivated. It will be forced into a continuous decision-making process, often based on inadequate data. It will find itself mediating the inconsistencies of academic versus commercial goals. It will be accountable to auditing agencies for its performance, risking Government money against no measureable objective standards. It will be Government acting as a broker between quasi-public institutions and the private business community!

"For Profit" Patent Management Organizations are well suited to transfer University generated technologies. The technology transfer business is speculative investment of highcost professional capabilities for potentially large rewards at the end of lengthy time sequences. Only "For Profit" PMOs have the incentive to take the risks. By permanent professional staffing, the "For Profit" PMO develops intimate relationships with individual researchers in the University community; it develops relationships of confidence and candor with industry. The "For Profit" PMO is the agent of the University to industry; it is correctly perceived to reflect academic goals in creating industrial relationships. It does not bear the onus of big Government. It mediates academic altruism and commercial reality.

5. Why won't publication, putting the invention into the public domain, effectively transfer technology? Why is protection necessary?

(a) Publication is passive; technology transfer is (to be effective) active. The inventor who publishes may believe he has done his job, and may concentrate his efforts elsewhere. Particularly, if his work was agency-funded and the grant has expired, the final report published, he may put the investigation aside as "finished." But the patenting procedure keeps the inventor involved through all stages of application and prosecution.

Transfer activities require that he become an advocate of the work, a "salesman" working with the PMO. It is often in the interplay of technical selling, when the industrial counterpart asks the hard questions and the inventor is forced to refine and expand and alter his concepts, that the "useful" invention as compared to the "legal" invention is made.

The people, through Government, have two basic motivations in funding research: to support the extension of knowledge for its own sake, and to enhance the public welfare by improving the delivery of goods and services to the population. For the first purpose, publication suffices. For the second, protection is essential.

It should be recognized that if Government chooses to become the transfer medium, within a limited period it will select the trouble-free, uncontentious road: the granting of nonexclusive licenses to all comers for token royalties. Big business will suffer no pain: it has the financial power to pick up and exploit a cheap license or ignore a technology entirely. Small business will suffer, because it is small business that needs the protection of a patent monopoly to survive and grow when surrounded by giants. Technologies which require substantial investments will not be brought from the University campus to the marketplace; the Government will have spent its "seed money" for no practical purpose. Foreigners, operating without the constraints we have imposed upon ourselves to protect life and environment, will obtain the fruits of our national investment for virtually no cost. They will use their inexpensive labor and Government subsidies to develop, produce and profit without reward to our Government (through taxable income) or to our institutions and our faculty inventors.

(b) Most University generated technology is "research," it is not "development." It is basic; it is embryonic; it must be scaled-up from the bench to the production facility; it must be tested in macrocosm; it must be evaluated economically; it must satisfy health and environmental requirements to protect workers and the using public. These activities may be done at the University under funding by the licensee, exclusively by the licensee, or in combination. In most instances, substantial sums of money must be dedicated to the project (without any assurance that the risk will in fact produce a reward). The licensee's capital risk is many times greater than the seed money invested by the agency. If life sciences, a pharmaceutical for which a funding agency may have granted \$200,000.00 or \$300,000.00 will require from two to seven years of industrial development and testing at a cost generally conceded to be from \$500,000.00 to \$1,000,000.00 per year. It is obvious that no company will commit itself to such a magnitude of investment without good reason to believe it can recover costs and ultimately make a profit.

Without protection, if more than one company decided to develop a technology, the economic waste of parallel effort would be obvious. Practically, however, without protection, no company will undertake the risk. The published technology becomes an academic curiosity.

If one assumes a patent is sought and the invention is licensed during its pendency, the licensee has the advantage

of confidentiality until the patent issues. It can develop the invention and initiate governmental approvals. Its competitors do not know who is working in the field. Publication in the learned journals after the application is filed, may generate inquiries. The competition may find out that "someone" has licensed a patent application and is developing the technology. An intangible benefit of the patent system arises: the competitor may start to "invent around" or "design around" the publication. The search for alternatives is stimulated.