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From University to Marketplace

University-developed inventions can be marketed, but commitment by institution is necessary

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Universities that have patent policy speak first and foremost of their responsibility to protect the public good. And so it should be. The university can accomplish this by conducting basic research and by promoting the utilization of the fruits thereof by means of the patent system. I am not here to argue the merits of the patent system but those that doubt that the patent system is an effective means of promoting utilization may find enlightening the following remarks from "The Role of Patents in Pharmaceutical Inventions" by Connor and Wolk.

"The U.S. drug industry leads the world in development of new medicines. During the 20 year period from 1941 to 1961, 544 major new drugs were made available. Nearly two-thirds of these originated in the United States, 316 came from the laboratories of the pharmaceutical industry, and only 25 came from educational and other nonprofit institutions and the government.

"In contrast, Italy and Russia, which offer no meaningful patent protection, have registered not one single significant pharmaceutical discovery in modern history."

The statement also illustrates that less than 5% of new drugs came from the university sector during that period. This is not unexpected or surprising when one realizes that U.S. federal funding to U.S. universities was not significant, that university researchers considered commericalization of their work unethical, that there was virtually no monitoring of university research, and that the primary U.S. agency for funding health care retained patent rights. However, Norman Latker, patent counsel for the U.S. Department of Health, Education, and Welfare (HEW), points out in a statement given on May 26, 1977 before the U.S. House Subcommittee for Science, Research, and Technology that despite a sharp reduction in new drug entities, from 65 in 1959 to 15 in 1975, as reported in a study by Schwartzman of Duke University, the university contribution has increased. What is the future outlook?

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For the past several years universities in the United States have received federal funding for research at approximately a $3-billion-a-year level. Yet, of the 100 leading U.S. universities that perform approximately 90% of all U.S. university research, only a small percentage have in-house programs wherein a systematic effort is made to identify, protect, and license inventions arising from such reasearch. Emphasis has been on what to do with a disclosed invention rather than in ferreting out the undisclosed. Notwithstanding, interest has not been lacking; witness the number of universities that attend the Dr. Dvorkovitz annual university-industry forum and the growth of the Society of University Patent Administrators (SUPA), a fledgling organization, some 2½ years old, that has about 100 representatives from the university sector. However, except for those with in-house programs, none has a full-time patent administrator serving as a focal point for the university.

Rule of Thumb

As a rule of thumb, there should be at least one invention disclosure for every one million dollars of university research. Clearly, a lot of disclosures are neither surfaced nor, if surfaced, acted upon. In view of the fact that the patent resource represents a source of unrestricted funds, which can be more fully appreciated when it is realized that it requires approximately $2-million in unrestricted endowment funds to match $100 thousand in royalty income, why don't we see a more concerted effort to develop and implement a patent program? The generation of such royalty income by U.S. universities for educational and research pursuits would clearly be in the public interest.

To answer the question, we must look to a variety of factors, including:

a. Vesting of patent rights.
b. The degree of visibility and support for a patent program.
c. The existence of a focal point.
d. The university infrastructure.
e. Equity sharing for the inventor.
f. The cost of patent applications.
g. The soft-money syndrome.
h. Available mechanisms for developing concepts.
i. The patent management organization.

Rights Vest

Let's look at each of these to obtain a better perspective of the problems and issues confronting the university

in surfacing inventions developed as a result of its research so as to promote their utilization in the private sector.

In many cases, patent rights vest in the grantor, the U.S. government. Although most agencies have a waiver procedure which allows the university to acquire rights to an identified invention, there are several undesirable features. First, the waiver procedure is an administrative burden which is time-consuming and exceedingly slow. The inability to act quickly often results in the loss of foreign rights and possibly even U.S. rights. True, the university can obtain permission to file a U.S. case so as to preserve rights but, in the event the waiver of U.S. rights is denied, costs are normally not reimbursable. Recent interest on the part of the U.S. government in foreign rights no longer will result in their automatic release. For example, the National Technical Information Service (NTIS) of the Department of Commerce has funds to file foreign applications and presently does so for agencies such as the U.S. Department of Agriculture (USDA) and U.S. Department of Health, Education, and Welfare. Finally, if invention disclosures may not be filed on forthwith, prospective licensees must be contacted, if at all, under the cloak of secrecy.

Fortunately, the issue of patent rights for the U.S. may become a non-issue through the efforts of Norman Latker, Patent Counsel for HEW, and Ray Thornton, Congressman from the state of Arkansas. Latker, as the chairman of the University Patent Policy Ad Hoc Subcommittee of the Committee on U.S. Government Patent Policy for the Federal Council for Science and Technology, has spearheaded the government-wide Institutional Patent Agreement (IPA) for universities. Any governmental agency could, on a voluntary basis, avail itself of the agreement, which is patterned on HEW's, unless the agency believes that it would be precluded from doing so by statute. Congressman Thornton introduced a bill in early 1977 to establish a uniform patent policy for inventions resulting from federally-funded research and development entitled the "Uniform Federal Research and Development Utilization Act of 1977." Thornton benefited from the recommendations of Latker's committee. The bill would allow the contractor, including the university, to acquire title to inventions resulting from federally-funded research. Said Thornton, "It is of serious concern to me that the legislative branch has failed to act to establish a mechanism whereby the fruit of federally-sponsored research and development can move forward with the researcher confident that his rights are protected under a uniform policy."

Little Incentive

Patent administration, when it exists within the U.S. university, most often reports to an office with a title such as the Office of Grant and Contract Administration. A recent, as yet unpublished, SUPA report on a survey of university patent policies bears this out. This is unfortunate because this office has little incentive to provide support. It can get no reward. In the best case, patent compliance required by the granting agencies, causes the office to identify someone in the group as the patent administrator; in the worst case, compliance is simply ignored. The lack of support is evidenced by the fact that the majority of SUPA members devote between 5% and 10% of their time to patent matters, yet they are the patent administrators for their respective universities. The net result is that patent administration if often a stepchild, tied to grants and contracts.

The lack of a patent administrator as a focal point who can devote full time to patent administration, creates great difficulties for the individual in the private sector who has the responsibility for establishing a liaison with the U.S. university. Dr. William Bissinger, in a talk given at the second annual SUPA meeting last year, made a telling point. In 1975 he visited with over 40 universities both in the United States and in Canada. He plans to make a return visit to those universities with a focal point and an agressive program; he may revisit those that had a marginal program; and he does not plan to return to those not having a focal point. The message is clear. Industry is willing to make an effort to promote the utilization of university inventions providing it can do so by making a reasonable effort within a reasonable time.

The university infrastructure which harbors many conflicting committees and viewpoints often sees patents as not worth the candle. Government compliance is often lax and rarely enforced. The path of least resistance becomes policy of inaction. Such a malaise generally can only be overcome by a commitment from the university president to support a patent program. In such a climate, there is little incentive for a principal investigator to submit an invention disclosure to his patent committee (often no such committee exists). University patent policy might allow the principal investigator to disclose his invention directly to a patent management organization. However, it is more likely that the principal investigator, who is already overburdened with reporting, will publish his findings in a journal and be done with it. That helps in obtaining grant awards; the role of patents is far less understood.

Equity Sharing

The lack of incentives in the form of significant equity sharing of royalties with both the inventor and/or his department is but another factor in the invention disclosure equation. Recent trends[1] in university patent policy exhibit a significant increase over the traditional 15% of gross royalties of equity to the inventor. More to the point, one can find a high correlation between active and successful patent programs and a policy that provides greater equity to the inventor. A singular exception is the Wisconsin Alumni Research Foundation (WARF), which in my opinion, is the best and most effective example of a patent program serving a single university or university system. WARF's long-term success and established expertise is the principal reason its long-standing arrangement with the University of Wisconsin has required no alteration.

The cost of a patent application by the university can be expensive with little likelihood of an early

1. "Survey of Patent Policies As They Relate to Royalty Income Paid the Inventor", prepared by Michael J. Pelczar, Jr., C. Wilbur Cissel, and Milton Goldberg, 8-15-73.

return on investment. Through a quirk in U.S. law, if industry files a patent application based on U.S. federally-funded research, the contractor is reimbursed for such costs, whereas the U.S. university would not be so reimbursed. The university sector has offered to provide funds not only for this purpose but for patent administration costs in general. Recently, the president of SUPA, in a letter to Dr. Donald S. Frederickson, Director of the National Institute of Health, suggested that the university overhead rates be adjusted upward by less than one-half of 1% to earmark funds for patent administration costs. Pressure by the government to reduce university overhead rates makes doubtful any increase, no matter how worthy. Presently the cost must be initially borne either by the university directly or by a patent management organization that hopes to recover its investment as an expense prior to distribution of royalties.

The soft-money syndrome causes nonsalaried researchers to spend a significant portion of their efforts in the generation of grant proposals. Typically, such a researcher is too busy surviving to be concerned with invention disclosures. The vicious cycle of grant proposal, grant award and publish makes one wonder when he/she has time to do research.

There are many good concepts at the U.S. university. Often, they are the unfunded byproducts of research. Typically lacking are mechanisms for developing these concepts to the feasibility demonstration stage at which point outside interest could be ascertained. Although most universities have small slush funds available for viable proposals, the funds are difficult to come by, especially for the young professor without a track record.

Few Techniques

Finally, the patent management organization, often unjustly maligned, has only a few techniques available to it to surface inventions at the university. Techniques, such as patent awareness, can help, but the job must be done by the university through commitment and support of its patent administrator who, in turn, must have the visibility that only support from the top can provide. It is in this area of visibility, in my judgment, that the patent management organization can be a significant factor.

What steps can be taken to increase the number of disclosures and to promote utilization of U.S. university-developed inventions?

The vesting of patent rights in the university under the proposed government-wide Institutional Patent Agreement (IPA) or better yet by way of U.S. congressional legislation would be an important step in speeding the innovation process. The administrative burden would be substantially lessened, invention disclosures could be protected early, and prospective licensees could be openly contacted immediately after the filing of a patent application. Under an IPA, the university as a quid pro quo must have a patent policy, a patent agreement for faculty and staff, and a patent administrator as the focal point for monitoring patent activities.

IPA or not, the university should create the position of patent administrator, and make the position full-time reporting to someone at least at the vice-presidential level. The patent administrator must have support from the top, i.e. the university's trustees and president, to acquire the visibility and cooperation with faculty and staff necessary to surface inventions and to provide for the long-term commitment that a patent program requires. The importance of the timely surfacing of inventions cannot be overemphasized. For example, it can mean the difference between acquisition of foreign rights and U.S. rights only. In view of the fact that the U.S. market represents only about a third of the world market for high-technology products, loss of foreign rights could have a considerable negative effect on potential total royalties to the U.S. university.

A full-time patent administrator, as the focal point for handling all university technology, provides several beneficial services to the principal investigator including relief from time-consuming burdens associated with patents. He provides him with basic information with respect to the patent laws and gets him to "think" patent, to become "aware." He assists in obtaining support for the demonstration of feasibility of his concepts. He promotes the utilization of the principal investigator's invention and generates royalties. The patent administrator enables individuals from the private sector to visit but one person to learn the latest developments throughout the university or to make inquiry about other developments.

Review Policy

The university should review its patent policy and, if appropriate, increase the equity to inventors and provide for departmental sharing as a suitable means for creating the necessary incentives for the principal investigator to disclose his invention to the patent administrator.

The cost of filing patent applications, unfortunately, is not reimbursable by the U.S. government or covered by the overhead rate. Both of these approaches require action by the government to increase costs at a time when there is pressure to reduce overhead rates. Another approach which can be implemented directly by the university involves use of the United States defensive publication program which can be coupled with an election to make the application international under the Patent Cooperation Treaty. The treaty is expected to be ratified by the requisite number of nations within the next year. Such an election could cut U.S. filing costs up to 50% and enable the university to postpone filing a decision; 30 months from the initial filing date with respect to the U.S. application, 20 months from the initial filing date with respect for foreign filings.

There are many instances where a U.S. university researcher has a concept with good commercial promise but lacks the small amount of funds necessary to demonstrate feasibility. Generally, it is too early to generate interest from the private sector. The researcher may not wish to disclose his invention to a U.S. governmental agency for fear of loss of rights under the Freedom of Information Act. Also, in many cases, the

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pt. 530. See *LES Eastern Europe Book, supra* note 8, Ch. VII at 210.
10. 50 U.S.C. App. §5.
11. 10 C.F.R. §§36-70.
12. 22 C.F.R. pt. 121. See, generally, *LES Eastern Europe Book, supra* note 8, Ch. VII at 208.
13. 35 U.S.C. §184.
14. See, generally, *LES Eastern Europe Book, supra* note 8, Ch. VII at 207.
15. See note 2 *supra*.
16. 15 C.F.R. §§370-399.2. All references hereafter to section numbers without further identification refer to sections of these Regulations.
16a. §379.3.
17. §379.4.
18. §379.1(a).
19. §379.1(b)(1).
20. §379.1(b)(2).
21. See Supplement No. 1 to Part 370 of the Export Administration Regulations.
22. 15 C.F.R. §399.1.
23. §379.5(f).
24. §379.3(a).
25. §379.3(b).
26. §379.3(c).
27. §379.4(a).
28. See §385.1.
29. §379.4(b)(1).
30. §379 .4(b)(2).
31. *Id.*
31a. *Id.*
32. *Cf.* §379.1, n.2.
33. §379.4(c).
34. §379.4(d).
35. See §§379.4(e)(1) and (2).
36. §379.4(e)(1), n.3; §379.4(e)(2), n.2.
37. §379.4(e)(2)(ii).
38. §379.4(e)(1); 379.4(e)(2)(iv).
39. §379.8(a)(2).
40. 27 Fed. Reg. 12487 (1962).

Effect of Government Data Policies

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Where a small but key amount of data covers 5% of the item to be reproduced or reprocured from a competitor, but a patent or several patents covers 60% of the hardware, you, as the owner of data may refuse the licensing of the data, thus forcing the government to accept the license under the patent as a condition to receiving a license under the data. Once the government accede to the licensing of those rights which you have, a reasonable royalty rate covering all of the hardware which is protected by either patents or data rights then becomes a significant amount of royalty. Where it is known that the government intends to second-source the military system which you are about to take a contract to develop, it is quite often made apparent to the contractor prior to the issuance of his prime contract that a reprocurement-data package, together with a license to use it for competition will be a downstream — the problem of the constant challenge of the data to be marked with limited rights. Although the government representatives like to insist that no data may be limited rights unless it properly falls within the category of data relating to items, components or processes developed at private expense, if there is a dispute as to whether you can prove this with clear and convincing evidence, the granting of a license can be accompanied with an agreement that the data is properly limited rights and the limited rights data to be furnished can be identified in many cases in advance of the contract or in the course of it.

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proposal would not be suitable for grant support by the government because it is the byproduct of research programs previously funded by the government and it is applied rather than basic.

Establishment of an internal funding program (or grant support from a patent management organization) made available by way of a grant award to university researchers under carefully controlled criteria can help bridge the gap between conception and utilization of those concepts with good commercial promise. Typically, a grant proposal should have as its objective the demonstration of feasibility at the end of one year at a cost (excluding overhead) of 15K to 20K normally used to support a postdoctoral candidate. The concept must be novel, should solve problems looking for a solution, and provide for a strong patent position. The commercial market should be large or growing. Finally, at the end of one year, the intent would be to license and/or to seek support from the private sector so as to subsequently bring the invention to the marketplace. Cost of the grant and any patent applications would be recovered prior to any distribution of royalties. Such a program, even if modest, would encourage disclosure of such breadboard concepts, enhance utilization of university-developed inventions, and increase the probability of generating royalty income since such proposals would have direct commercial application.

In conclusion, U.S. university-developed inventions can be surfaced and brought to the marketplace if the university is willing to make the necessary commitments. A commitment by the president of the university to make a patent program visible is a prerequisite to success.