"Technology Transfer: Payoffs or Pitfalls"

Remarks to the
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By Michael J. Remington*

"Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that have been made in laboratories throughout the United State with the help of taxpayer's money. More than anything, the single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

The Economist Technology Quarterly[1]

In the United States, technology transfer is understood not only by government officials, university administrators and faculty, and pharmaceutical and biotechnology companies, but also increasingly by foreign observers who, in a Tocquevillian sense, are more keenly aware (than are Americans) about what is good (and bad) in our society.

As regards technology transfer, Americans are vaguely aware that economic growth depends on our ability to develop and apply new technologies, and that our universities are

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* Michael J. Remington is a partner in the law firm of Drinker Biddle & Reath LLP. He is the former long-time Chief Counsel of the House Judiciary Committee's Subcommittee on Courts and Intellectual Property. Among other clients, he represents the Wisconsin Alumni Research Foundation ("WARF") and the American Council on Education. He also serves as a consultant to the Pharmaceutical Research and Manufacturers of America ("PhRMA").

[1] (U.S. Edition) December 14, 2002 at p. 3.

envied around the world. The returns – in terms of the flow of expertise, and the creation of new products and start-up companies – have been impressive. Based on data reported to the Association of University Technology Managers ("AUTM") for the year 2000, and reflected in the AUTM Licensing Survey, we know that certain universities excel at commercializing the inventions of their professors: Stanford University, the University of California system, the University of Wisconsin-Madison (through the Wisconsin Alumni Research Foundation ("WARF")), the University of Washington (Washington Research Foundation), Massachusetts Institute of Technology ("MIT"), the State University of New York Research Foundation, the University of Pennsylvania, the Texas A&M University System, Johns Hopkins University and the University of Michigan. In 2000, universities and non-profits spent a record $29.5 billion on research and development. Sales of goods developed from products that were transferred from university research centers resulted in revenues of a whopping $42 billion, and U.S. universities, research institutes and hospitals recouped almost $1.2 billion in gross income. Much of this income was subsequently made available to fund further research and educational activities.

The benefits of university innovation are palpable and increasingly understood. Dr. James A. Thomson, Associate Professor at the University of Wisconsin, was even featured on the August 20, 2000 cover of *Time* magazine for the wizardry of his stem cell discoveries. In 2000, 347 products – the fruits of university research and technology transfer to the private sector – were made available. Among these, three examples suffice:

- A breakthrough device to increase the comfort and accuracy of mammograms;
- An environmentally-safer alternative to treated wood; and
- A deicing technology for safer air and land transportation.

Finally, in 2000, innovations by universities resulted in 6,375 new U.S. patent applications, a 15% increase from the preceding year; invention disclosures rose to 13,032, a 6% increase.

The federal government is a key part of the technology transfer equation, contributing almost 60% of university research support. In 2000, government sources contributed $18.1 billion, an increase of 8% over the previous year. In response perhaps to the practical limits of federal funding, the growth rate of industry-sponsored research at U.S. universities has also been impressive. Collaborative research has become the norm rather than the exception.

However, aggregate statistics do not provide a detailed road map for an individual university to maximize intellectual assets. In fact, even large research universities are not currently getting rich from intellectual property royalties. Few universities benefit from "blockbuster" patents. Of almost 21,000 licenses active in 2000, less than 1.0% generated income in excess of $1 million.

Arranged marriages between universities and corporations, under the stern eye of the federal government, are not ideal. Universities' fundamental goals are to teach students, to develop new knowledge and to disseminate that knowledge. Corporations' underlying missions are to produce profits and to build value for shareholders. The role of the federal government is to benefit the public and promote the general welfare of the people.

Many university administrators know more about their football team than technology transfer. The Bayh-Dole Act stimulates memories of two fine Senators long departed from public service; however, responding to an essay question about the Act that bears their names would be a hazardous undertaking for university presidents and administrators. Many licensees of university technologies would be equally endangered with a failing grade.

The Bayh-Dole Act

U.S. patent law is a national law (it would make no sense to have different rules in different states) and, like other laws, reflects societal changes. Patents provide inventors the right to exclude others from making, using, selling, offering for sale, or importing a new invention for the life of the patent, which today is twenty years from the date of the filing. A patent, the society's reward for a discovery, is a property right with clear boundaries. It provides a way for a patent holder to secure income from the commercial exploitation of an invention. Parties that are interested in practicing an invention for which they have no ownership may obtain rights by entering into a licensing agreement with the patent holder.

Almost two decades ago, Congress enacted the seminal Patent and Trademark Laws Amendments of 1980 (Public Law 96-517), as later amended in 1984 (commonly known in government and academic circles as the Bayh-Dole Act), to promote patents in the utilization and commercial exploitation of inventions arising under federally-funded research by non-profit organizations, such as universities and small businesses. By creating a uniform patent policy among federal agencies that fund research, Congress linked together the federal government, universities, small businesses and the corporate world. More than any other factor (and there are others), the Bayh-Dole Act contributes to growth of technology transfer.

The Act is balanced in its approach. On one hand, universities may retain title to and market the inventions they create using federal research funds and may collect royalties on the inventions, and, on the other hand, federal agencies are permitted to grant exclusive licenses for federally-owned inventions to provide increased incentives to businesses. As regards the non-profit sector, rights to an invention created in whole or in part with federal funds cannot be assigned without the permission of the government (except that an assignment may be made to

an entity, like a university foundation, that has as its primary function the management of inventions). The Act permits exclusive licenses that may be more financially advantageous than nonexclusive ones (exclusive licenses, however, are frowned upon by many federal agencies). The Act also requires the sharing of royalties generated by the invention with the inventor and the use of the balance of the royalties, after expenses, for support of educational or scientific research activities. In all cases, the federal government retains a royalty-free, non-exclusive license to practice the invention for governmental purposes and also reserves so-called "march-in" rights if a contractor (university or small business) has not taken "effective steps to achieve practical application of the invention," or the invention is "necessary to alleviate health or safety needs which are not reasonably satisfied" by the contractor or licensee. To date, the federal government has never exercised "march-in" rights. The Act additionally provides protections against disclosure by federal agencies of confidential information pertaining to a subject invention while a university (or other contractor) is pursuing a patent.

The benefits of the Bayh-Dole Act are far-reaching. Universities annually receive billions of dollars in direct federal funds. Federal agencies also provide R&D funding to non-profit institutions other than universities (such as research hospitals, independent laboratories and other research-specific institutes). Some of these non-profits are managed by universities. Prior to enactment of Bayh-Dole, universities filed fewer than 250 patents every year (in comparison to the more than 6,300 filed in 2000). Patents granted to universities are increasing annually, and generally fall into key technology areas and involve life-saving advances. As explained by Carl Gulbrandsen (WARF's managing director), "... those patents, since they arise primarily from the results of basic research, can often afford the basis for whole new products or even industries, as in, for example, the biotechnology industry." The certainty of intellectual property title in

universities has promoted a closer relationship with the private sector. At the same time, the Bayh-Dole Act protects fundamental academic freedom to conduct research and reinforces the mission of the academic community to discover and transmit knowledge to the betterment of the public. A university is free not to patent new knowledge that is patentable, and a patent can operate to put an invention in the hands of the public that was responsible for developing it.

The Bayh-Dole Act does not explicitly protect the patent interests of large, for-profit enterprises engaged in government research. Nonetheless, in 1983 President Ronald Reagan issued a memorandum to the heads of executive agencies informing them that, to the extent permitted by law, it would be the policy of the administration to apply the patent policy of the Bayh-Dole Act to any invention made with federal funding and cooperative agreements irrespective of the size of the recipient's business or its non-profit status. In 1987, the President issued Executive Order 12591 which, among other matters, requires executive agencies to promote commercialization in conformity with the 1983 memorandum.

Despite its benefits, the Bayh-Dole Act has a chorus of critics and detractors.

- Drug-price advocate James Love demeans current practices: "the taxpayers pay to invent a promising drug, then give a monopoly to one company and the company's role? To agree to sell it back to us...."
- Well-known columnist Ellen Goodman writes that encouraging faculty members to combine "science and business, nonprofit and profit," is also mixing "altruism and chumphood." She speculates that Dr. Jonas Salk might be considered a chump for giving away his work on the polio vaccine.
- Two intellectual property law professors (Arti Rai and Rebecca Eisenberg) propose that "the time is ripe to fine-tune the Bayh-Dole Act to give funding agencies more

latitude in guiding the patenting and licensing activities of their grantees." In essence, the professors ask for a congressional clarification that patenting and exclusive licensing are not always the best way to go.

- A recent article in the *New Republic* by a Harvard Medical School professor emeritus (Arnold Relman) and senior lecturer (Marcia Angell) opines that "whether the Bayh-Dole Act has been an overall success is questionable."
- Over the past two decades, legislative proposals have been floated in Congress to require that the prices charged for technical advances developed with federal funds are reasonable.

As for any congressional enactment, especially ones that generate policy debates, oversight is necessary (and indeed is required by House and Senate rules). Statutes are never cast in concrete, nor immune from public debate, as has occurred last Congress about whether state universities should be allowed to bring lawsuits for monetary damages in federal court to enforce their patent rights or whether patent administrative formalities for prescription drugs should be tightened to the detriment of pharmaceutical companies and universities. A recent letter to the House Committee on the Judiciary indicates an "urgent" need for increased congressional oversight of compliance with and enforcement of the Bayh-Dole Act. The letter comes from one of the Act's detractors who alleges that the failure to comply with the Act's directions is costing taxpayers billions of dollars every year.

Technology transfer challenges

Today, technology transfer is a very big business. In the face of great complexity and breadth, success has been achieved by some universities. Success, however, has not been

uniform. Places like MIT, the University of California system, Stanford and Wisconsin (all of which had technology transfer programs prior to the Bayh-Dole Act) routinely stimulate inventive activities and harvest millions of dollars in royalties. Others do not. Universities in both camps face crossroad bifurcations with one path leading to a promising business venture but away from a healthy academic environment, and a second path heading towards the intellectual commons with a doomed commercial enterprise. Some carve new paths. In any event, the number of academic technology transfer entrants with little experience in patenting and licensing is growing.

With faculty found increasingly at the busy intersection of business interests and academic obligations, university presidents should inquire about both the upside and downside of the increasingly close ties between academic and private industry. A strategic alliance between Cal-Berkeley and a Swiss pharmaceutical company was pilloried in the press as the "corporatization of the university" without concrete evidence that academic research had been compromised. When perception becomes reality, university officials must react.

Today taxpayer support for basic research must compete with homeland security and national defense in a weak economy. Funds may be diverted from biotechnology and health care to cyberterrorism and germ warfare. Nonetheless, opportunities abound due to the basic research strengths of American universities. So do technology transfer controversies.

The patent law provides a civil battleground for resolution of controversies. Battles are being fought and won (or lost) in at least two significant areas: (1) collaborative research; and (2) experimental use and research.

Collaborative Research. Today, collaborative research among private, public and not-for-profit entities is quantifiably important to the U.S. economy. Despite a clear trend towards

scientific collaboration and the practical necessity for such collaborations, a 1997 decision of the U.S. Court of Appeals for the Federal Circuit threatens to stifle such collaborative activity. This decision is *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d. 1396 (Fed. Cir. 1997). *Oddzon* interpreted subsection 103(c) of the Patent Act to hold that prior art under subsections 102(f) and (g) could be used to determine the obviousness of an invention where: (1) there was no common ownership or assignment of the invention and information being shared among collaborators; and (2) the information exchanged was not publicly known.

That holding made it clear that information under subsections (f) or (g) could invalidate a patent in the circumstances of joint collaborative research. The *Oddzon* decision creates an ominous threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity, be it a university or corporation. Accordingly, while the need for collaborative research in the public interest is apparent, the *Oddzon* decision blows a cold wind on collaborative efforts among universities, the private sector and the government.

The solution is a legislative one. The *Oddzon* court itself invited Congress to review its decision stating that "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any later intervention by Congress ...)." 122 F.3 at 1403.

Congress will soon consider a clarifying amendment to section 103(c) that would result in increasing the flow of information among scientists at different institutions; increasing the collaboration of scientists both within and outside a given institution; promoting collaborations between the university and the private sector; promoting collaborations between government laboratories and the private sector as well as with the university sector; and enhancing the

national pool of knowledge due to the greater unhindered flow of information among scientists and researchers.

To be fair, the proposed amendment should be prospective only. Further, the amendment should not affect any final decision of a court or the U.S. Patent and Trademark Office that is rendered before the date of enactment and, should not affect the right of any party in any case pending prior to the USPTO or a court on the date of enactment to have rights determined on the basis of the substantive law prior to the date of enactment.

Experiment use and research. Another Federal Circuit decision, *Madley v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), has also created controversy. In *Madley*, the Federal Circuit denied the experimental use exception in the patent law to all academic scientific research, even when that research is manifestly noncommercial. The court held that the exemption is not available to nonprofit universities because scientific research at those universities serves legitimate educational purposes.

A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), wherein the Federal Circuit held that the experimental use exemption did not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of td drug. Congress determined that *Roche* had inappropriately narrowed the exemption and overruled it in the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) (the "Act"). The Hatch-Waxman Act itself represented a congressional compromise (between innovator and generic pharmaceutical companies) to create a level playing field on which the companies operate. The Act added Section 271(e)(1) to Title 35, of the United States Code:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

Effectively, a "safe harbor" was created that serves to insulate activities "reasonably related to the development and submission of information" to certain governmental agencies necessary to obtain regulatory approval.

Under conventional rules of statutory construction, exceptions or exemptions should be read narrowly. A narrow reading would indicate that section 271(e)(1), although worded broadly, was designed to immunize the bioequivalency testing needed to secure FDA approval of generic drugs (which was the issue raised in *Roche v. Bolar*). Some courts have so held. The Act's legislative history reveals that the "only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. H. Rep. No. 98-857 (Part II), 90th Cong., 2d Sess. (1984).

Courts have departed from a narrow reading, finding that section 271(e)(1) should be read broadly. *See, e.g., Amgen, Inc. v. Hoechst Marion Rousssel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). A recent case (*Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.* 2001) U.S. Dist. LEXIS 19361 (S.D. N.Y. 2001) held, in essence, that the plain meaning of section 271(e)(1) covers all information required to obtain approval of a drug (in essence, basic research, animal testing, human clinical trials, synthesis of new drug candidates, their initial testing, and a determination of whether drug candidates should be pursued). A party which develops such information but decides not to submit an application for approval is also protected as long as the

development was done to determine whether or not an application for approval would be sought. In effect, new product screenings are covered, and exempt from allegations of patent infringement.

Potentially, patents claiming research tools (such as cell-based assays) and biologics/genomics are implicated, and potentially jeopardized. Given the success of major research institutions for engaging in basic research and also in developing research tools and applications, universities and non-profits should closely monitor developments relating to section 271(e)(1).

The ability of university/non-profit patent holders to protect their patents may be severely compromised by both a broad research exception (*Bristol-Myers*) and a non-existent one (*Madey*). On one hand, a dilution in the strength of patents, especially those related to basic research tools and applications could be harmful to the public interest because investments will not be made in the commercial exploitation of these tools and applications. On the other, the inability to conduct noncommercial research for teaching purposes could chill academic innovations. Ultimately, serious public policy issues may have arisen that warrant the attention of the United States Congress.

A Practical Short-Term Approach

Here are a few practical suggestions for preserving success and avoiding catastrophic failures. At the outset, it should be noted that many lawyers, professors and citizens take the law for granted and feel that they can have little or no impact on the political process. While this feeling in a time of "big" government and campaign finance abuse is understandable, it must be overcome. The law is your vehicle. Please spend as much time on its care as you do your car.

1. Encourage technology managers to monitor overall trends and developments in intellectual property law, both domestically and internationally, and to share those trends with each other. Managers should continue to disseminate to the public their successes (and shortcomings). The annual AUTM Licensing Summary is a step in the right direction; but more can be done.

2. Respect federal laws and regulations. If intellectual property is created as a result of federal funding, regulations make the grantee university (rather than the department or school), or a university foundation, the responsible entity for invention reporting and property administration. Failure to respect regulatory provisions may result in the loss of patent rights. Because the utility of patents varies among industrial sectors (they are more important in the pharmaceutical and chemical industries than they are for semiconductors and aerospace), different university departments (even in the sciences) may have different views. In any event, universities must apply standardized compliance rules across all federally-funded activities.

3. Self-regulation of federally-funded activities must take place. No simple federal agency is responsible for monitoring and managing technology transfer activities government-wide. Each federal agency involved in technology transfer designs its own program and may tailor it to meet the agency's specific mission. The administration of federal technology transfer law is generally decentralized, and technology transfer personnel of recipient entities must recognize that each agency that awards R&D funds is required to ensure that grant recipients comply with the Bayh-Dole Act.

4. Reporting requirements of the Bayh-Dole Act and, by extension, Executive Order 12591 should be respected. On two recent occasions, the Government Accounting Office ("GAO") has found that contractors and grantees were not always complying with reporting

requirements. GAO found that databases for recording the government's interests in inventions were inaccurate, incomplete and inconsistent and, in some instances, some inventions were not recorded at all. To a certain extent, reporting problems were systemic. GAO informed Congress, that it may wish to improve the reporting process. In light of the GAO reports, the law and regulations should be respected.

5. Technology transfer entails partnerships most often through licensing with the private sector and entrepreneurial risk-taking in a very competitive environment. The edge between rightful action and wrongdoing is often razor sharp. Universities must be prepared offensively to enforce rights through litigation and defensively to be sued. The private sector will inevitably be an interested (or aggrieved) party. In any event, careful licensing that reflects the balances in the law and regulations should be pursued.

6. Real and perceived conflicts of interest should be avoided. The desire to maximize financial returns and customer satisfaction, felt especially strongly by large corporations and their shareholders, may occasionally interfere with academic freedom and the core university mission of educating students. Since the enactment of the Bayh-Dole Act, institutional conflicts of interest have grown. On a continuing basis, university administrators should monitor (or assign a monitoring role to a responsible party) to avoid interferences destructive of the public trust.

7. "Best practices" should be established to promote respect for the law, efficient administration, and effective licensing. Organizations like the Licensing Executive Society could play a pivotal role here. So do others like the Association of American Universities, the Council on Government Relations, and the Association of American Medical Colleges.

Conclusion

Science matters, but it does not just happen. Despite arguments that "science is at an end," any scientific endeavor must be incubated, nourished and mentored. Few researchers work alone. The Bayh-Dole Act provides an ideal habitat. Certain things never change: scientific breakthroughs come from the genius of the human mind. Today's reality is that scientific research requires infusions of substantial amounts of cash, and that the academic community operates in a larger ecology inhabited by the federal government, state and local officials, and the private sector. Cultural disparities between the players are significant, but not necessarily adversarial. Reconciliation of the twin goals of developing the intellectual commons as a public good and protecting technology as a property right during a limited time is possible. Licensing plays an instrumental role in achieving this balance.

Like science, laws also do not just happen. They are the product of our constitutional system of governance. Key policy officials are elected periodically by the public, and are accountable to the citizenry. Involve yourself (or your organizations, universities or companies) in that process or do not complain when successful technology transfer is hindered by government intervention, legal changes, or market forces.

Thank you.