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THE STATEMENT OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION ON

The Role of Federally-Funded University Research in the Patent System

BEFORE THE SENATE COMMITTEE ON THE JUDICIARY

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The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide the perspective of its members on the role of federally-funded university research in the patent system. BIO represents over 1,100 companies, universities and research institutions using biotechnology to research and develop cutting edge healthcare, agricultural, industrial and environmental products and applications.

From the perspective of the biotechnology industry, it has been the strength and predictability of the U.S. patent system that has led to the translation of publicly-funded research into useful, commercial products. This unparalleled patent system in conjunction with the Bayh-Dole Act has served as a basic tool for economic development and job creation in the United States.

The biotechnology industry pin-points its origin to two seminal events: The passage of the Bayh-Dole Act and the landmark Supreme Court decision of *Diamond v. Chakrabary*, where the Court opened the door for the patenting of key biotechnology inventions including biological materials and living organisms. Both of these events occurred in 1980. By allowing universities and research institutions to patent and retain title to their inventions, and allowing flexibility in licensing without excessive government intervention, the U.S. patent system in conjunction with the Bayh-Dole Act provided the necessary impetus for public institutions to transfer technology, and provided the inclination for the private sector to develop publicly-sponsored research. The result of these two events include, among other things, the existence of hundreds of innovative therapeutics, diagnostics and tools, industrial processes and agricultural products for the benefit of society, as well as hundreds of thousands of new, high-paying American jobs.

The biotechnology industry is one of the most research and development (R&D)-intensive and capital-focused industries in the world. The industry is primarily made up of small companies that are unprofitable and that lose billions of dollars annually. Yet it holds the promise for a cutting-edge cure for Alzheimer's, drought resistant crops, or the next alternative energy source. With over 1,400 companies, many of which spun out of university research, the U.S. leads the world in biotechnology R&D. In 2005, the U.S. biotech industry spent $20 billion on research and development, and since its inception roughly three decades ago, has put into the hands of the public hundreds of new therapies and vaccines and medical diagnostic tests based on biotechnology. In addition, there are more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis. The industry has already developed dozens of insect-resistant crops and environmentally-friendly industrial applications.

All of these accomplishments have occurred despite the decades-long development time, massive investment needs, and complex regulatory processes the industry must overcome

to bring its products and applications to market. The Milken Institute, in a 2006 report entitled "Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization,"[1] identified five key factors that contribute to the successful commercialization of university biotechnology research: a consistent and transparent national innovation policy that recognizes intellectual property protection and promotes entrepreneurial capitalism; the availability of funding and venture capital; biotechnology clusters not restricted by geographic borders; robust university technology transfer mechanisms; and patents and licensing.

The U.S. system of commercializing scientific discoveries has made it the world leader in the area of biotechnology in large measure because it takes into account the factors identified by the Milken Report. However, this was not always the case. Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980. Prior to enactment of this legislation, publicly-funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. There was little incentive for business to undertake the financial risk to take these inventions and develop them into commercial products. Prior to Bayh-Dole, only 4% of the patents that resulted from federally funded research were commercialized. Since Bayh-Dole, not only has the volume of invention resulting from federally-funded research increased enormously, but also the percentage of those inventions being commercialized has increased ten-fold to around 50%. For instance, in 2005, 17,382 inventions were disclosed, 10,270 new patent applications were filed (59%) and 4,932 licenses and options were granted (48% of new patent applications filed). The total pipeline of active licenses from all the years up to and including 2005 was over 28,000.[2]

The U.S. system of transferring federally-funded research to private companies for research and development as set forth in the Bayh-Dole Act has been so successful that it has become a template for innovation and economic development for other enterprising countries such as India and China. The Milken Report shows that, while universities in the United States have clearly set the standard in commercializing research, other countries, particularly in Europe and Asia, have recognized the role of universities in spurring the biotechnology industry. The study suggests that, in order for the U.S. to maintain its leadership in innovation, it must continue to fund research and university technology transfer offices, encourage the transfer of innovative research to the private sector, and ensure strong intellectual property protection.

BIO urges this Committee to consider the immense value derived from this well-crafted system of strong patent protections and the resulting technology transfer over the past 25 years, and to ensure that the ability of this system to provide future benefit to the

[1] Mind to Market Study. http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep
[2] AUTM U.S. Licensing Survey, FY 2005; www.autm.net

American public and the world community is fully preserved. In its oversight capacity, this Committee should carefully consider how pioneering policies like strong patent laws and the Bayh-Dole Act have helped to create the biotechnology industry and U.S. leadership in this area, as well as the broader economic and societal benefits.

The Role of Patents in Biotechnology

In BIO's view, efficient transfer of federally-funded research is intricately linked to strong IP protections and free market incentives. In the context of the Bayh-Dole Act, patents serve as the legal instrument used in the transfer of technology, information and know-how. Commercializing an invention in the biotech sector is a lengthy process requiring significant amounts of capital, often in the hundreds of millions of dollars. While government funding and research is critical in biotech R&D, substantial additional financing from the public and private capital markets is required to actually take the product from the idea stage to one that can be used by the public.

Let's take as an example a typical healthcare-related biotech discovery. A researcher, typically in a publicly-funded laboratory, discovers a gene whose presence is only found in a particular type of cancer. The researcher also determines that the presence of this gene signals the presence of a quantifiable amount of a particular protein. Translating this initial discovery into a therapeutic application can take decades and hundreds of millions of dollars. However, it is at this early stage when the promise of a therapy is on the horizon that the researcher can seek patent protection on the various aspects of the discovery. By way of a patent, the researcher can generate interest in the further development of this potential new product by, for example, out-licensing the invention, or forming a spin-off company focusing on the R&D of this early-stage discovery. In both cases, the patent is the asset that creates a forward trajectory for the project. In the former case, an interested company partner would, among other things, review the strength and scope of the IP protecting the early-stage discovery to determine the worth of the investment. In the latter case, the IP generates the interest of institutional investors, venture capitalists, or other partners encouraging the creation of an early-stage company. In any event, the early-stage, publicly-funded discovery is now on its way to development. Of course, the road to development from this point is long and torturous, and often fraught with set backs, but the transfer of technology is complete and the wheels are set in motion.

From this point on, patents play a significant role in the investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical and pharmaceutical sector through potential sales of the drug/product, the market exclusivity prospect through patent protection, other forms of marketing exclusivity (such as orphan drug exclusivity), or other means to gauge the strength and predictability of patent protection.

The ancillary benefits of this ecosystem to the economy in the form of jobs, tax revenue and new companies should not be overlooked. According to the Association for University Technology Managers' (AUTM) annual report[3], the Bayh-Dole Act continues to create hundreds of companies and tens of thousands of new jobs annually. Virtually every state has a biotechnology center or initiative. In its policy statement on July 24, 2007, the National Governors Association recognized the import of strong IP and university technology transfer fostered by Bayh-Dole as catalysts for innovation and R&D.

If the major policy objective of the Bayh-Dole Act is to use the patent system to promote the commercialization and utilization of inventions arising from federally-supported research or development, then the biotechnology sector is an exemplary measure of its success. The Bayh-Dole Act provides one of the key environments for biotechnology companies to take the risk of investing in biotechnology R&D. It provides the lure of market exclusivity as the incentive for companies to work in cooperation with public institutions. There is little misunderstanding of the primary obligation that companies have under Bayh-Dole to *commercialize* the licensed technology. This point is solidified by the statute's provision that failure to commercialize a licensed federally-funded invention can be the basis for government march-in rights.

BIO believes that the patent system and the Bayh-Dole Act are working quite well. However, there are potential threats to this finely-tuned system. As an example, the Congress is currently considering patent reform legislation that, in its current form, could negatively impact commercialization of publicly-funded research by undermining the strength, value, and predictability of patent protection. This would, in turn, make it much less likely that companies and venture capital companies would invest in risky, cutting-edge research, resulting in publicly-funded research sitting on laboratory shelves. BIO recently testified before this Committee about its views on patent reform, and the university technology transfer community has weighed in with similar concerns.[4]

There also are potential opportunities to enhance the technology transfer system. BIO believes that consistent and transparent implementation of the Bayh-Dole Act, together with a cataloguing of "best practices" and successful partnerships, would provide more efficient transfer of technology. Congress should consider funding studies that would aid in the identification and compilation of such best practices and identify how best to support the technology transfer offices in their overall mission.

In this spirit, BIO cautions against policies that would weaken market incentives through excessive government intervention. We can point to lessons learned in the 1990s in studying the Bayh-Dole Act. Concerns that healthcare reform proposals from the early 1990s could have led to price controls caused serious perturbations in the market for biotechnology investment. The impact of potential price controls on the biotechnology

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[3] See AUTM 2005 Survey, *supra.*

[4] BIO's Patent reform statement; http://bio.org/ip/domestic/20070606.asp

industry was immediate and powerful. The capital markets crashed and investment in biotech research nearly dried up.

A similar result occurred in 1999 when President Clinton and Prime Minister Blair were cited in the press as supporting the notion that certain classes of patented genetic information should be freely available to all at the time the human genome was "unraveled." Despite a clear correction by the President the next day, it took six months for the biotechnology capital markets to recover.

In both cases, a threat to free-market protection and undermining intellectual property rights drove investors away from biotechnology research. The Bayh-Dole Act was designed to facilitate the transfer of publicly-funded research to the private sector for further development and commercialization. The careful balance set forth in the Act has been hugely successful. We have learned from history that excessive government intervention can disincentivize biotechnology companies from undertaking the huge risks to bring innovative products and services to all Americans.

CONCLUSION

The U.S. system of protecting innovation and technology transfer has worked well over these 25 years. The Senate Judiciary Committee is to be commended for undertaking this examination of this system, which the world aspires to emulate. BIO appreciates the opportunity to provide insight into the impact of how this system has given birth to the biotech industry and to describe the nature of the industry and its contributions to the improvement of the human condition. BIO's members are strong supporters of the current system of technology transfer as governed by the Bayh-Dole Act, which has opened the door to the creation of many biotechnology companies that have developed important advances and cutting-edge solutions to some of the world's most intractable problems. We caution against policies that would weaken market incentives through excessive government intervention. We urge Congress to continue its far-sighted approach to innovation as it continues oversight of this very important issue.