

Patent Reform and its Effect on University Technology Transfer

Enacted in 1980, the Bayh-Dole Act has been called “the most inspired piece of legislation to be enacted in America over the past half-century.”¹ This act has allowed universities to retain title to inventions made under federally funded research programs, which enabled these educational institutions to join with industry, thus ensuring that inventions made with taxpayer money would be available to the public. Proposed reforms threaten to stifle the significant progress universities have made as a result of the act, however.



Before the Bayh-Dole Act was passed, the government retained title to technology that had been invented under federally funded research programs. Even though the government did issue nonexclusive licenses to this technology, few companies were willing to invest in development and commercialization because of the lack of exclusivity in the marketplace. As of 1980, fewer than 5 percent of the federally funded patents had been licensed for development.² Congress became concerned with the federal government’s inability to promote new technology and decided that the public would benefit from a policy that allowed universities to retain ownership of their inventions and to work with industry to develop the inventions for the marketplace.



Under the act, universities can patent inventions that the federal government has funded in whole or in part. Universities can then issue exclusive licenses to companies that want to develop and commercialize the new technology. The university must give licensing preference to small businesses and must ensure that any company given an exclusive license to patent a product for sale in the United States substantially manufactures the product in the United States. The inventor must receive a share of the licensing revenue, and the university must use the remainder to fund additional research and education. The federal government retains a nonexclusive, nontransferable, and irrevocable right

to use the invention on behalf of the United States throughout the world. Finally, the federal government retains “march-in rights” that allow federal agencies to assume ownership of inventions when universities fail to take appropriate steps to make an invention available to the public.

Since the passage of the act, universities have had a significant impact on the development and commercialization of new technologies. Today, approximately 4 percent of patents are granted in favor of universities,³ and more than 230 universities now have technology transfer offices that work with industry to license university-owned patents.⁴ Examples of technology originating from university-industry partnerships include recombinant DNA technology, Citracal® calcium supplements, an artificial lung surfactant, and various therapeutic cancer treatments.⁵ The act has enabled universities to spin off more than 5,000 companies that have introduced an average of 1.25 products per day into the market and have created more than 26,000 jobs. The overall effect of the Bayh-Dole Act has been to contribute more than \$40 billion annually to the American economy.⁶

Despite the enormous success attributable to the Bayh-Dole Act, it is not without its critics. Some argue that Bayh-Dole is overly broad, because it allows universities to patent research discoveries that can be used as downstream research tools in addition to end products. These critics claim that such upstream research tools should be available in the public domain, where they can further downstream research and development. Others argue that the act makes universities less likely to publish their work before applying for a patent in order to keep the intellectual property proprietary. Thus, in the eyes of these critics, the Bayh-Dole Act will lead universities to abandon their primary duty of disseminating knowledge in favor of obtaining revenue from commercially licensing the fruits of their research.

Notwithstanding these criticisms, there is little evidence that universities have shifted their primary emphasis away from education, nor is there any indication that technology transfer activities have impeded university research. In fact, organizations such as the National Institutes of Health and the Association of University Technology Managers have set forth guidelines for universities that are involved in technology transfer. These guidelines include ensuring broad access to research results, avoiding conflicts of interest,

minimizing exclusive licensing of upstream research tools, and advancing research and deploying innovations for the public benefit. All in all, the public has benefited greatly from technology transfer activities conducted at universities.

Congress is currently reviewing several patent reforms that would weaken the act. First, Congress is considering moving from the current system of awarding patents on a “first-to-invent” basis to awarding them on a “first-to-file” basis. This race to the U.S. Patent and Trademark Office would inevitably harm universities whose limited resources prohibit them from patenting an invention before its commercial viability is known. Furthermore, universities would be less inclined to present their early-stage research results for fear that another party might beat them to the filing office. The reform contemplated today would hinder collegial sharing of research results and place enormous pressure on universities, which already carry heavy financial burdens.

Second, Congress has proposed other reforms that threaten to weaken the value of patents in general, which in turn would inhibit a university’s ability to license its technology. Congress has proposed language that would expand the prior user rights defense to infringement to include situations in which there has been “substantial preparations for commercial use.”⁷ Congress has also proposed reform that would increase a party’s ability to challenge a patent that has been issued. Under this reform, a party could challenge an invention’s patentability at any time during the life of the patent. Furthermore, Congress is considering eliminating the presumption of patent validity that was traditionally present in post-grant opposition proceedings.

These reforms devalue patents and create uncertainty in patent ownership. Such uncertainty decreases a university’s ability to license its technology to the commercial sector, because investors would be less likely to risk spending the capital necessary to commercialize technology that has been created by a university. Such a result would frustrate the primary purpose of the act and would sharply decrease universities’ financial ability to conduct new research as their licensing revenue declines. In today’s age of double-digit tuition increases and restrictions on faculty salaries at major public universities throughout the country, there can be no doubt that public funding would not make up for any such loss of licensing revenue. However, according to James Zanewicz, director of the University of Louisville’s Office of Technology Transfer, there is much more than licensing revenue at stake:

Bayh-Dole, and the current patent system, have allowed [u]niversities to achieve their primary goal: moving innovations off the shelves and into the marketplace to benefit society. Without them, the biotech industry would not be the burgeoning industry we now have, and in Louis-

ville alone we have created 18 new startup companies (with many more in the works) through our license and option deals. These companies sponsor research at U of L, prevent brain-drain by hiring our graduates, and are truly helping to shift us from a manufacturing mindset into a knowledge economy.

Overall, the Bayh-Dole Act has been a resounding success since it was implemented more than 25 years ago. As time goes on, it is likely that parts of the act will need to be reformed. If Congress does choose to reform the law, one can only hope that it will do so in a way that protects and promotes the primary objectives of the Bayh-Dole Act by continuing to offer strong protection for patents as well as incentives for universities, faculty, and the commercial sector to continue developing and licensing new innovations for the benefit of the public. **TFL**

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Endnotes

¹*Innovation’s Golden Goose*, THE ECONOMIST at 3 (Dec. 2002).

²U.S. Government Accounting Office, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities*, p. 3 (May 1998), available at www.gao.gov/archive/1998/rc98126.pdf.

³Arundee S. Pradhan, director, Technology and Research Collaborations, Oregon Health Sciences University, Testimony before the U.S. House of Representatives, Comm. on Science and Technology, Subcomm. on Technology and Innovation, 110th Congress, Washington, D.C., July 17, 2007.

⁴Dr. Charles F. Louis, vice chancellor for research, University of California at Riverside, *The Role of Federally Funded University Research in the Patent System*, Testimony before the U.S. Senate, Comm. on the Judiciary, 110th Congress, Washington, D.C., Oct. 24, 2007.

⁵Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*, October 1999.

⁶Pradhan, Testimony, *supra* note 3.

⁷S. 1145, 110th Cong. § 5 (as reported in the U.S. Senate, April 2007).