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Technology Transfer

The Bayh-Dole Act has been especially celebrated in the past few months for its 30th anniversary and for the benefits that it brought to the biotechnology industry and to the world. There are, however, scholars, members of Congress, and members of industry who have criticized the legislation for actually stifling research. This report presents comments about the Bayh-Dole Act from both those who write in blogs, “Repeal the Bayh-Dole Act? Are you out of your mind?” to those who have suggested that it be repealed or at least modified.

Bayh-Dole Benefits Seen But Some Cite Unintended Negatives

The 30th anniversary of the Bayh-Dole Act was celebrated by a congressional resolution (4 LSLR 1085, 11/19/10) and other events (4 LSLR 1210, 12/17/10).

The House of Representatives’ resolution credited the Bayh-Dole Act of 1980, which gave universities, small businesses, and nonprofits the opportunity to own intellectual property developed with federal funding, with creating the biotechnology and information technology industries and helping the United States dominate them. It said that the act “created a better world,” pointing to the development of “over 150 new drugs, vaccines, or in vitro devices, including the hepatitis B vaccine, cisplatin, carboplatin and taxol anticancer therapeutics, laser eye surgery devices, the Palmaz balloon expandable stent, and many more” under the act.

The act “remains critical to the future well being of the United States,” said the resolution, introduced by Rep. John Conyers Jr. (D-Mich.). “Congress reaffirms both its support for this landmark legislation and the critical role that innovation, entrepreneurship, and job creation hold for the future of the United States, and its commitment to the policies and objectives of that Act.”¹ The House had passed a similar resolution for the law’s 25th anniversary.²

Speaking at the celebration sponsored Dec. 1, 2010, by the Association of University Technology Managers (AUTM), former Sen. Birch Bayh (D-Ind.) listed the accomplishments of the legislation:

- more than 6,500 companies were created, with about 600 created last year in the midst of a serious recession, or an average of about two new companies every working day of the year;
- more than 5,000 products were created;
- more than 130 new drugs, vaccines, or devices protecting public health around the world were developed;
- new industries such as biotechnology were created; and
- at least \$187 billion was added to the U.S. gross national product while a minimum of 279,000 jobs were created in just a nine-year period.³

And yet, there have been critics of the legislation. Seven days after Bayh’s remarks, in an article published in *Nature*, Bhaven N. Sampat argued that the Bayh-Dole Act had just “replaced one set of frictions with another—it eliminated restrictions on patenting and technology-transfer licensing in favor of promoting excessive patenting and overly restrictive licensing. The

¹ H. Con. Res. 328, Nov. 15, 2010.

² H. Con. Res. 319, Nov. 16, 2005.

³ Birch Bayh, “Remarks Delivered at the Washington Convention Center at Event Celebrating the 30th Anniversary of the Bayh-Dole Act,” Dec. 1, 2010.

growing aggressiveness of some technology-transfer offices in asserting their patents is now souring relationships between universities and industry, especially in information technology.”⁴

Some have suggested modifying or even repealing the legislation. Testifying at a congressional hearing June 10, 2010, Neil D. Kane, president and co-founder of Advanced Diamond Technologies Inc., recommended modifying the Bayh-Dole Act to require that any license agreements executed for subject technologies become publicly accessible. “This should be legislatively mandated,” Kane said. “Universities will vigorously oppose it, but it will level the playing field and reduce transaction costs across the board. This action will dramatically shorten the time needed to get companies formed and licenses executed. From the university or federal lab standpoint, the public contract should change from ‘the government funded it but we own it,’ to ‘if we want to profit from retaining title to the intellectual property which was funded by the taxpayers, then we have to be willing to tell the taxpayers what we charged them for it.’”⁵

David P. Swenson of Robins, Kaplan, Miller & Ciresi LLP, Minneapolis, who wrote an amicus brief in the ongoing Supreme Court case *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*, U.S., No. 09-1159, cert. granted 11/1/10, which concerns aspects of the Bayh-Dole Act, told BNA in an e-mail that he had some concerns about varying interpretations of the act. “Certainly most people seem to think the Bayh-Dole Act has worked well and produced an economic benefit for the country over the past thirty years,” he said. “But what struck me in studying the act, reading all the briefs, and presenting these amici’s arguments, is that the various Bayh-Dole stakeholders apparently lacked any clear shared understanding all these years of exactly how the act operates.”

Benefits Largely Undisputed. In his Dec. 1 remarks, Bayh recalled how he and then-Sen. Bob Dole (R-Kan.) had investigated complaints that important discoveries made at American colleges and universities were being prevented from fully benefiting the taxpayers supporting the research. They found that there were more than 20 federal patent policies then in place across the various federal agencies but that all were based on the premise that inventions made with government support should be taken away from the inventing organization and licensed non-exclusively by the bureaucracy. The comptroller general told the two senators that there were 28,000 inventions “caught in this web,” with less than 5 percent ever licensed for development, and that not a single new drug had been commercialized when the government owned the patent.

The ultimate legislation was codified in 35 U.S.C. §§ 200-212, and implemented by 37 C.F.R. § 401. Among other things, the act reversed the presumption of title by giving a university, small business, or non-profit institution the opportunity to pursue ownership of an invention that had been created by use of federal funding.

⁴ Bhaven N. Sampat, “Lessons from Bayh-Dole,” *Nature*, Vol. 468, pp. 755-756 (Dec. 8, 2010).

⁵ Neil D. Kane, Testimony to House Subcommittee on Research and Science Education, Committee on Science and Technology Hearing, “From the Lab Bench to the Marketplace: Improving Technology Transfer,” June 10, 2010.

In addition to the statistics Bayh cited, a number of research reports over the years have cited the benefits and overall success of the Bayh-Dole Act. A 2009 study funded by the Biotechnology Industry Organization showed a \$187 billion positive effect on the U.S. gross national product and a \$457 billion addition to gross industrial output from 1996 to 2007 as a result of university technology licensing, which BIO attributed to the Bayh-Dole Act.⁶

A 2010 AUTM study indicated that in fiscal year 2008, universities filed more patent applications, were involved in more startups, and generated more income in large part due to biopharma-related activity than the previous year, which the AUTM president attributed to the Bayh-Dole Act in a press statement.⁷

Unintended Consequences. But also over the years, there has been criticism of the legislation. Critics usually will acknowledge the good intentions of the law and that it has brought benefits, at least to some. In their criticism of the law, they tend to focus on its unintended consequences. Some have suggested that the Bayh-Dole Act actually has restricted access to research. There have been accusations that the legislation has added a monetary incentive for universities and researchers that could increase conflicts of interest and prevent disinterested inquiry.

Sampat wrote in a 2003 paper, “The political history of Bayh-Dole reveal[s] that it was passed based on little solid evidence that the status quo ante resulted in low rates of commercialization of university inventions. More remarkably, the hearings completely neglected the economic importance of the public aspects of university research, and ignored the possibility of potential negative effects of increased patenting and licensing on open science and on other channels of technology and knowledge transfer.”⁸

Sampat added, however, that while he believed that efforts to emulate the Bayh-Dole Act in other countries were unjustified, he thought “tinkering” rather than “major changes” would be sufficient for the United States.

In a 2006 paper, David C. Mowery, Richard R. Nelson, Sampat, and Arvids A. Ziedonis wrote, “The theory behind Bayh-Dole was that companies needed exclusive patent rights to develop and commercialize the results of university research, a theory that flies in the face of the position that patents tend to restrict use of scientific and technological information, and that open publication facilitates wider use and application of such inventions and knowledge.”

The authors suggested that more of what universities formerly would have put in the public domain is being patented and subject to administrative procedures that could restrict the diffusion of these research results.⁹

⁶ Biotechnology Industry Organization, “The Economic Impact of Licensed Commercialized Inventions Originating in University Research, 1996-2007,” released Oct. 28, 2009 (3 LSLR 1103, 11/6/09).

⁷ Association of University Technology Managers, “Survey of University Technology Managers,” released Feb. 24, 2010 (4 LSLR 208, 3/12/10).

⁸ Bhaven N. Sampat, “Private Parts: Patents and Academic Research in the Twentieth Century,” <http://www.card.iastate.edu/research/stp/papers/SAMPAT-Nov-03.pdf>.

⁹ David C. Mowery, et al., “The Growth of Patent and Licensing by U.S. Universities: An assessment of the Effects of the Bayh-Dole Act of 1980,” 30 *J. Res. Pol.* 99, 117 (2006).

The growth of the U.S. biotechnology industry was so substantial that some Organisation for Economic Cooperation and Development (OECD) countries announced their intention to create their own laws modeled on the Bayh-Dole Act. In a 2008 paper, Anthony D. So, Sampat, Arti K. Rai, Robert Cook-Deegan, Jerome H. Reichman, Robert Weissman, and Amy Kapczynski concluded that policies to develop public sector research and development are context-specific and that it was unclear whether any of the positive effects of the Bayh-Dole Act in the United States would arise in developing countries following similar legislation.¹⁰

Legislation modeled on the Bayh-Dole Act was proposed in India, and the Universities Allied for Essential Medicine wrote a white paper urging caution because of flaws in the Bayh-Dole Act. Krista Cox summarized the paper:

We expressed concerns that the Bayh-Dole model focuses too narrowly on patenting and licensing and also was overly-broad in scope. We further noted that the patent regimes often do not provide appropriate public health safeguards . . . Additionally, the white paper contained suggestions to address the problems of the Bayh-Dole model. We encouraged the Indian government to include a statutory research exemption and strong language for march-in rights [the government's right to "march-in" and on its own license the rights in the invention to other parties under certain circumstances] in the [Indian legislation]. We suggested that the government consider mandating or encouraging open source licensing and open access publishing. Also, the paper noted that the Indian government should not place such a heavy emphasis on patenting and licensing and consider alternative mechanisms instead.¹¹

Michael Crichton, National Research Council. Dr. Michael Crichton, a best-selling author who became globally known for writing techno-thrillers that frequently dealt with medical and/or genetic research such as *The Andromeda Strain* (1969), *The Terminal Man* (1972), and *Jurassic Park* (1990), is a widely-quoted critic of the Bayh-Dole Act.

Crichton's last novel to be published before his death in 2008 was titled *Next: a novel* (2006), which follows many characters, including transgenic animals, in the quest to survive in a world dominated by genetic research, corporate greed, and legal interventions where government and private investors spend billions of dollars every year on genetic research. It begins with a disclaimer that "This novel is fiction, except for the parts that aren't," and ends with an afterword in which Crichton addresses the Bayh-Dole Act.

Bayh-Dole was always of uncertain benefit to the American taxpayers, who became, through their government, uniquely generous investors. Taxpayers finance research, but when it bears fruit, the researchers sell it for their own institutional and personal gain, after which the drug is sold back to the taxpayers. Consumers thus pay top dollar for a drug they helped finance. . . . The Bayh-Dole legislation anticipated that the public would receive a flood of marvelous life-saving therapies such that the investment strategy would be justified. But that hasn't happened. Instead, the drawbacks far outweigh the benefits.¹²

¹⁰ A. So, et al., "Is Bayh-Dole Good for Developing Countries? Lessons from the Experience," *PLoS Biology* 6(10):e262, Oct. 28, 2008.

¹¹ Krista Cox at <http://essentialmedicine.org/blog/indian-bayh-dole-bill-update>, Aug. 18, 2010.

¹² Michael Crichton, *Next: a novel* (2006), p. 423.

Crichton concluded that secrecy now pervades research and hampers medical progress. "Universities that once provided a scholarly haven from the world are now commercialized—the haven is gone. Scientists who once felt a humanitarian calling have become businessmen concerned with profit and loss. The life of the mind is a notion as quaint as the whalebone corset," Crichton wrote.

An important statement about the Bayh-Dole Act came when the National Research Council criticized the law's failure to provide proper oversight. In its report, "Managing University Intellectual Property in the Public Interest," issued Oct. 5, 2010, the NRC said that because the Bayh-Dole Act did not establish a stable, effective framework for government oversight, such responsibilities should be created (4 LSLR 934, 10/8/10).

"There should be a clear assignment of federal government oversight responsibilities, perhaps by Executive Order, including ensuring consistent implementation of federal technology transfer laws by all agencies; reviewing agency diligence and actions with respect to Determinations of Exceptional Circumstances, government use rights, and exercise of march-in rights; revisiting the Department of Commerce regulations implementing several provisions of the Bayh-Dole Act, including the conditions for access to and use of data gathered about inventions; heading an interagency committee on technology transfer that would, for example, evaluate and develop a government-wide position on proposed changes to the Act or system; and reviewing with other agencies and with representatives of research universities and relevant professional groups the data that should be collected from universities," the report concluded.¹³

In his Dec. 1, 2010, statement, Bayh acknowledged, "The oversight authority Bob and I established in the bill is not functioning as Congress intended. Unfortunately, the report wrongly faults the law for this lapse." Bayh said the real cause of the problem came as the expert staff left, and "succeeding policy officials appeared disinterested in Bayh-Dole, and oversight gradually fell off the radar screen."

Congressional Action? Kane and others have called on Congress to modify or repeal the legislation. The Tea Party movement, which was so influential in the 2010 midterm elections, also has taken up the cause.

In a Sept. 21, 2010, posting on the website with the name "The Liberty Journal," a poster identified as AI put up an article titled "So, Tea Party Patriots Have No Clue How to Initiate Government Fiscal Responsibility?" and included in his or her long list of recommendations "repeal the Bayh-Dole Act and allow the U.S. taxpayer to collect royalties for technology developed with taxpayer money."¹⁴

In 2002, Sen. Ron Wyden (D-Ore.), as chairman of the Senate Committee on Science, Technology, and Space, was vocal in his desire to repeal or at least modify the Bayh-Dole Act. He particularly singled out for rebuke drug companies that he said used taxpayer-funded research to gain an advantage in a fiercely com-

¹³ National Research Council, "Managing University Intellectual Property in the Public Interest," National Academies Press (2010), p. 94.

¹⁴ <http://thelibertyjournal.com/2010/09/21/so-tea-party-patriots-have-no-clue-how-to-initiate-government-fiscal-responsibility/>.

petitive market and then turned and charged consumers exorbitant prices for essential medicines.

At a committee hearing on advanced manufacturing and biotechnology April 14, 2003, Wyden said to one of the panelists, “Bayh-Dole, I am convinced that Bayh-Dole did not work for anybody. I do not think it works for taxpayers who are concerned about the rate of return. I do not think it works for companies that get caught up in the morass of the bureaucracy and red tape, and I think it does not work very well for the universities who are frustrated and would very much like to have more of these partnerships. Tell me, if you could wave your wand over Bayh-Dole, and you mentioned it in your testimony, you could see that I was interested in it, what would you do to improve Bayh-Dole for the big stake holders companies, taxpayers, and universities?”¹⁵

Wyden’s office did not respond to BNA’s request for further comment.

A review of legislative history indicates no bills have been introduced over the past 30 years to specifically repeal or modify the Bayh-Dole Act. Republican control of the House and its increase of seats in the Senate, along with the general thinking that Republicans are pro-business, would suggest that revision of the law in the current session is not likely. An unknown aspect of this is the influence of the Tea Party movement on the Republican-controlled House.

Supreme Court to Visit Bayh-Dole. There has, however, been some court-related activity addressing the legislation. In one case, the Supreme Court will review the Bayh-Dole Act for the first time.

Rather than the unintended consequences of the law, legal actions, both current and potential, ask the court to look at the “meaning” of the law’s language.

While activity concerning availability of a drug treatment for Fabry disease patients currently is at the federal agency level, the attorney representing the patients has suggested that agency actions make one provision of the law appear to be meaningless.

Patients petitioned the National Institutes of Health to allow manufacturers to produce Fabrazyme under a march-in license as authorized by the Bayh-Dole Act because of shortage of the drug due to manufacturing problems at Genzyme’s facility. Under Bayh-Dole, the government can “march-in” and issue patent licenses on its own when the holder of a patent that resulted from the research is not “reasonably” satisfying U.S. health or safety needs. NIH denied the petition, stating that FDA regulations would require potential manufacturers of Fabrazyme to obtain FDA approval, which could take up to three years and make the granting of march-in rights to manufacturers futile (4 LSLR 1195, 12/17/10).

The patients then petitioned the FDA Jan. 19 to allocate full doses of the drug to U.S. patients before exporting it (5 LSLR 76, 1/28/11).

On the denial of the first petition, the patients’ attorney C. Allen Black told BNA, “The U.S. Department of Health and Human Services is supposed to reconcile the [Federal] Food, Drug, and Cosmetic Act with the Bayh-Dole Act, and it controls both NIH and FDA. And

yet in its memorandum NIH effectively says, sorry, our sister agency is too slow and there’s nothing we can do about it. We think that creates a substantive problem with the Bayh-Dole Act.”

In their second petition, the patients commented on the rejection of the first one, stating, “Thus, despite the Bayh-Dole mandate of protecting public health from monopolists that undersupply the market of publicly-funded inventions, the NIH cites FDA regulations as frustrating the purpose and effect of march-in for public inventions.”

The *Roche* case now before the Supreme Court began with the U.S. District Court for the Northern District of California May 28, 2008, ruling invalid three Stanford University HIV-monitoring patents that the university asserted in a patent infringement suit against Roche Molecular Systems Inc. (2 LSLR 445, 6/6/08). In September 2009, the U.S. Court of Appeals for the Federal Circuit held that Stanford had no standing to bring a patent infringement lawsuit because one of the inventors assigned the university his rights before the invention was created (3 LSLR 985, 10/9/09). The appeals court rejected Stanford’s arguments based on the Bayh-Dole Act, saying that the government’s interest in the ownership cannot override a prior assignment.

Stanford appealed to the Supreme Court for certiorari, asking the question, “Can a federal contractor university’s statutory right under the Bayh-Dole Act in inventions arising from federally-funded research be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor’s rights to a third party?” (4 LSLR 630, 7/2/10). The court granted certiorari (4 LSLR 1017, 11/5/10).

Briefing on the case was completed Feb. 1 (*see related item in the Stanford v. Roche Update section*).

Title by Operation of Law? Swenson, who wrote an amicus brief on behalf of the American Association of University Professors, told BNA, “The Bayh-Dole Act addresses a deceptively simple question: who should control the rights in inventions that originate out of work by certain types of contractors—individuals, small businesses, or nonprofits including universities—under federal funding agreements? Sens. Dole & Bayh drafted the act because under existing law, policies, and agency behavior, the federal government collected patent rights and tucked them away to gather dust. Sen. Dole issued several press releases in 1978-79 excoriating agencies for ‘suppressing lifesaving drugs and medical devices developed under support from [N.I.H.]’ The impact of the Act [is] not in dispute, and what ultimately appears responsible for the Act’s perceived success, is that Bayh-Dole wrested control over these patents away from the government and facilitated licensing.”

Swenson continued, “But the question is, where have those rights resided all these years while so many lauded the Act’s success? Section 202(a) of the act allows a contractor to ‘retain title to any subject invention.’ Of course a ‘subject invention’ must be an ‘invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement,’ not merely any invention touched by federal money during its development (35 U.S.C. § 200(e)). But how did the contractor get the title in the first place that it may ‘retain?’ ”

Stanford and the amici supporting it argue that, where it says “retain,” the Bayh-Dole Act in fact takes

¹⁵ Testimony at hearing before the Senate Committee on Science, Technology, and Space (S. Hrg. 10-8-822), First Session, April 14, 2003.

title by operation of law from inventors of a “subject invention” and vests it with the contractor under a federal funding agreement, Swenson said. “In reality, though, essentially every university has maintained an intellectual property policy that sets the conditions for notice and assignment of rights, Bayh-Dole notwithstanding, when an employee invents something,” Swenson said. “Roche and the amici supporting it contend these assignments have defined the rights contractors held, and thus “retain” under the Bayh-Dole Act. Either way, generally speaking—at least until this case—contractors obtained the necessary rights to license inventions for commercialization.”

But even though the court will review the wording of the Bayh-Dole Act, Swenson suggested that the ulti-

mate review of the legislation should not be by courts of law.

No one knows what the Supreme Court will decide about what the Bayh-Dole Act truly has meant these past 30 years by “retain title,” Swenson said. “Regardless of how the court reads the Act and interprets the legislative intent in 1980, however, the more important work should take place back in Congress. The legislative branch, with a fresh round of input from all of the stakeholders, should decide anew how to revise the Bayh-Dole Act to best serve today’s evolved economic realities,” Swenson said.

BY JOHN T. AQUINO