

REMARKS

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REMARKS BY JON SODERSTROM*

Senator Birch Bayh has made the most significant impact on the U.S. and global economy of any individual who has ever come before and who lives today, full stop. That's an amazing accomplishment. We have heard about all the legislative feats that he accomplished. We've heard about what an amazing legislator, attorney, and public servant he was. But, there are very few human beings who have had the impact on our economy that Senator Bayh had. It's an amazing accomplishment and something that we should be in awe of.

I'm going to give you a few statistics. I'm not going to overwhelm you; I'm going to bring it down to a personal level. I promised Kitty that I wouldn't cry. Because when I was thinking about this the other day, it's hard. If you knew Senator Bayh, he wore his emotions on his sleeve, and we have cried together.

Here are just a couple statistics that should blow you away. The Bayh-Dole Act¹ unleashed the technologies that were being developed in universities in a way that no one probably could have imagined. It was immediate and it was dramatic. The year was 1980. Prior to 1980—and I know because my entire career arc has followed the senator's accomplishments—I was at graduate school studying the economy and what patents were doing, et cetera. At that time, the federal government, by law, was the owner of all intellectual property created with federal dollars and, as a result, it had created 28,000 patents.² Less than 5 percent of those patents had ever been licensed or commercialized, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention.³ That is “because the government would only grant nonexclusive licenses to patents it owned,” so

* Managing Director, Office of Cooperative Research at Yale University. These remarks were made during the Symposium entitled *Celebrating the Impact of Senator Birch Bayh: A Lasting Legacy on the Constitution and Beyond*, hosted by Fordham Law School's Feerick Center for Social Justice on October 16, 2019, at Fordham University School of Law. The text of these remarks has been lightly edited and footnoted. For an overview of the corresponding Tribute, see *Foreword: Celebrating the Impact of Senator Birch Bayh: A Lasting Legacy on the Constitution and Beyond*, 89 FORDHAM L. REV. 1 (2020).

1. 35 U.S.C. §§ 200–212.

2. U.S. GEN. ACCT. OFF., TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 3 (1998), <https://www.gao.gov/assets/230/225671.pdf> [<https://perma.cc/VK69-EBKP>].

3. *Id.*

“a wall was erected between academic and corporate research.”⁴ Companies refused to invest the significant time and resources needed to receive regulatory approval in nascent technologies that could be simply copied by others, especially foreign firms, obtaining the same nonexclusive license. Research was often described in this period as being “contaminated” by federal funding because of the government’s licensing policies.⁵ In spite of the fact that a large portion of that was spent on the Department of Health and Human Services and the National Institutes of Health, no drug could trace its lineage to a patent license based on research that had been supported by the federal government.⁶ That’s before Bayh-Dole.

From 1980 on, things changed. Universities became the owners of the patents, and the reason was simple: Senator Bayh recognized that you needed to put the intellectual property in the hands of the people who actually invented it. Those are the people who understand it; those are the people who are passionate about it; those are the people who had the perseverance. They would be the ones who would drive things forward. Subsequent to the passage of the law, over 12,000 new companies were started.⁷ Interestingly enough, over 6000 of those companies still exist.⁸ Many of them are household names that you would recognize, such as Genentech and Amgen, just in the life sciences area. Importantly, 153 new drugs have been discovered, have gone through the clinical development process, and are on the market after receiving Food and Drug Administration (FDA) approval.⁹

I’m going to talk to you about one. I’m going to use it to show what happened and why this law is so important. There was a scientist at Yale University, where I’ve worked for many years now. His name was William Prusoff. In the 1950s, he had this amazing insight about how to create new types of drugs to combat infectious disease by interfering with the DNA-synthesis mechanism.¹⁰ He invented the very first antiviral drug,¹¹ but no one filed a patent. It was to cure a form of blindness that was caused through a defect in a DNA mechanism.¹² It never got commercialized; nobody cared and nobody did anything with it.

4. Vicki Loise & Ashley J. Stevens, Commentary, *The Bayh-Dole Act Turns 30*, SCI. TRANSLATIONAL MED., Oct. 6, 2010, at 1, 1, <https://stm.sciencemag.org/content/scitransmed/2/52/52cm27.full.pdf> [<https://perma.cc/7Y5G-4L83>].

5. *Id.*

6. *Id.*

7. See Dr. Dipanjan “DJ” Nag et al., *The Evolution of University Technology Transfer: By the Numbers*, IP WATCHDOG (Apr. 7, 2020), <https://www.ipwatchdog.com/2020/04/07/evolution-university-technology-transfer/id=120451> [<https://perma.cc/GH7U-72XK>].

8. See *id.*

9. Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEW ENG. J. MED. 535, 538–39 (2011), <https://www.nejm.org/doi/pdf/10.1056/NEJMsa1008268> [<https://perma.cc/B8KD-4DAJ>].

10. William Grimes, *W.H. Prusoff, Who Developed AIDS Drug, Is Dead at 90*, N.Y. TIMES (Apr. 6, 2011), <https://www.nytimes.com/2011/04/07/health/research/07prusoff.html> [<https://perma.cc/FX8R-LJ3E>].

11. *Id.*

12. *Id.*

Now, we're in 1984 and many of you here will remember what the crisis of the 1980s was: AIDS. Nobody knew what it was or how it was transmitted. It was a death sentence. If you got it, you were going to die. The only question was when. There were no drugs to treat it because nobody knew how it worked. Many academic medical centers, like my own, mobilized resources to start to understand exactly how the virus was transmitted and replicated and how it attacked the body's immune system. They started to try everything they could possibly think of to stop it. Nothing worked.

Lo and behold, two scientists at Yale—Bill Prusoff and Tai-Shun Lin—went into the freezer and found a compound called stavudine that had been developed many years before but had not been commercialized.¹³ It had just been distributed among academics.¹⁴ It had been developed by Jerome Horowitz at the Karmanos Cancer Center in Detroit.¹⁵ He thought it would be a cancer drug, but it failed.¹⁶ Inspired by Bill's pioneering work in the 1950s on antiviral therapy for disease treatment, he and Dr. Lin decided to try it to treat the AIDS virus.¹⁷ They discovered this was the first time any chemical had ever killed the virus with this level of activity.¹⁸

There were a couple of problems, including that this was not a drug that could be used on humans and that it was very difficult to make.¹⁹ Because the two scientists had developed a relationship with Bristol Myers Squibb (BMS) and the Bayh-Dole Act encouraged researchers to work with companies to license patent rights for work they did, they approached BMS and asked if they would be interested in working on the drug.²⁰ BMS said they would be interested if the scientists could solve those problems.²¹ Over the next nine months to a year, they solved all of the problems.²² In 1984, BMS took the drug, finished the preclinical development package, went to the FDA, and got the first fast-track approval for this drug.²³ It became

13. *Id.*

14. *See id.*

15. *Id.*

16. *New York Times Profiles Yale Professor Who Discovered Stavudine*, KAISER HEALTH NEWS (Mar. 20, 2001), <https://khn.org/morning-breakout/dr00003525/> [<https://perma.cc/4VFU-DUVJ>].

17. *Id.*

18. William Prusoff, Opinion, *The Scientist's Story*, N.Y. TIMES (Mar. 19, 2001), <https://www.nytimes.com/2001/03/19/opinion/the-scientists-story.html> [<https://perma.cc/UYJ3-PEN2>].

19. Andrew Z. Michaelson, *The Law of the Lab: Using Zerot to Inform Technology Transfer* 55–57 (2002) (Third Year Paper, Harvard Law School), <https://dash.harvard.edu/bitstream/handle/1/8963875/michaelson.pdf?sequence=1&isAllowed=y> [<https://perma.cc/ASC4-A78M>].

20. *See* Prusoff, *supra* note 18; Michaelson, *supra* note 19, at 55–57.

21. *See* Prusoff, *supra* note 18; Michaelson, *supra* note 19, at 55–58.

22. *See* Grimes, *supra* note 10; Prusoff, *supra* note 18.

23. *See* Grimes, *supra* note 10; Michaelson, *supra* note 19, at 55–58.

known as Zerit.²⁴ It was the very first effective medication against HIV-AIDS. It also became the very first component of what became the AIDS three-drug “cocktail.”²⁵ With that, what was a death sentence became a manageable disease. That’s amazing. That has saved millions of lives.

In 1980, when Senator Bayh was advocating for this change, he was doing so because it just seemed like the right thing to do—to unleash the entrepreneurial spirit behind this intellectual property. What he didn’t realize was the impact it was going to have on individuals all over the world. This drug, Zerit, which has now been followed by even better variations, ended up stemming the AIDS crisis in Africa, eastern Asia, and other parts of the developed world.²⁶ This was a miracle. None of this would have been possible without the Bayh-Dole Act.

Subsequent to that, the Bayh-Dole Act has created about a trillion dollars’ worth of economic activity and 5.8 million jobs.²⁷ Think about those statistics for a minute. This is incredible for a small piece of legislation for which he is hardly even recognized. Everybody knows about Senator Bayh’s work on various amendments to the Constitution, which was great. But this Act changed lives, and I’m one of them. Thank you.

24. U.S. FOOD & DRUG ADMIN., ZERIT® (STAVUDINE) 1 (2008), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020413s025,020412s0331bl.pdf [https://perma.cc/DV7R-ABA9].

25. Prusoff, *supra* note 18.

26. *See, e.g.*, Chronicle, *After an Uproar, Price of AIDS Drug Falls in Africa*, YALE MED. MAG., Spring 2001, at 4, 4, https://medicine.yale.edu/news/yale-medicine-magazine/ym_sp01_348411_43933_v1.pdf [https://perma.cc/H9HG-FWW8]; Sheila Davey, *Medicines for All, Not Just the Rich*, 79 BULL. WORLD HEALTH ORG. 377, 377 (2001), [https://www.who.int/bulletin/archives/79\(4\)377.pdf?ua=1](https://www.who.int/bulletin/archives/79(4)377.pdf?ua=1) [https://perma.cc/YX9D-3AFG]; Melody Petersen & Donald G. McNeil, *Maker Yielding Patent in Africa for AIDS Drug*, N.Y. TIMES (Mar. 15, 2001), <https://www.nytimes.com/2001/03/15/world/maker-yielding-patent-in-africa-for-aids-drug.html> [https://perma.cc/528Y-MG4G].

27. LORI PRESSMAN ET AL., THE ECONOMIC CONTRIBUTION OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996–2017, at 3 (2019), https://autm.net/AUTM/media/About-Tech-Transfer/Documents/Economic_Contribution_Report_BIO_AUTM_JUN2019_web.pdf [https://perma.cc/BJ8U-KEJB].