

KEY IDEAS:

The “Bad Old Days” Before Bayh-Dole .....1

Purpose of Bayh-Dole Act .....2

Statutory Structure.....2

Bayh-Dole in Practice.....3

Bayh-Dole in the Federal Circuit.....3

Bayh-Dole at the Supreme Court.....4

Conclusions.....4

HAS THE BAYH-DOLE SPIGOT RUN DRY?

The Bayh-Dole Act has been in the news as the patent bar awaits the Supreme Court’s decision in *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*<sup>1</sup> “What, exactly, is the Bayh-Dole Act?” you may have wondered. Or, less charitably, you may have asked yourself, “Did Bayh and Dole run against Clinton and Gore in 1996?” If either of these characterizations has you pegged, consider these claims:

- “Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980.”<sup>2</sup>
- “More than anything, this single policy measure [the Bayh-Dole Act] helped reverse America’s precipitous slide into industrial irrelevance.”<sup>3</sup>
- “Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980.”<sup>4</sup>

With that type of build up, the Bayh-Dole Act ought to be added to your IP IQ.

The “Bad Old Days” Before Bayh-Dole

On Dec. 12, 1980, the Bayh-Dole Act was passed in the waning days of a lame duck session of Congress.<sup>5</sup> Prior to Bayh-Dole, a U.S. company seeking to use government-funded research to develop a new product faced “a bewildering array of 26 different sets of agency regulations governing the rights to use such research.”<sup>6</sup> In many instances, such an inventor’s rights to his discoveries “automatically vested in the United States” by “operation of law.”<sup>7</sup> Publicly funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public.<sup>8</sup> But, the government lacked the resources to commercialize its own patents.<sup>9</sup> And, although the government had a formidable portfolio of approximately 28,000 patents, only about 5% were commercially licensed.<sup>10</sup> As a result, there was little incentive for businesses to take the risk to develop a product.<sup>11</sup>

Not surprisingly, by 1980 the U.S. was in a period of recession and “economic malaise,” and there had been “an especially significant decline in total U.S. expenditures for research and development, as measured in constant dollars since 1970.”<sup>12</sup>

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1 583 F.3d 832 (Fed. Cir. 2009), cert. granted, \_\_ U.S. \_\_, 131 S.Ct. 502 (2010).  
 2 *Innovation’s Golden Goose*, ECONOMIST, Dec. 12, 2002 (Technology Quarterly).  
 3 *Id.*  
 4 *The Bayh-Dole Act: The Next Twenty Five Years: Before the H. Science and Technology Subcomm. On Technology and Innovation*, 110th Cong. 1 (August 27, 2007) (statement of the Biotechnology Industry Organization) (hereinafter BIO).  
 5 See Clifton Leaf, *The Law of Unintended Consequences*, ECONOMIST, Sept. 19, 2005.  
 6 H.R. REP. No. 96-1307, Pt. 1 at 1 (1980).  
 7 *FilmTec Corp. v. Hydranautics*, 982 F.2d. 1546, 1550 (Fed. Cir. 1992), cert. denied, 510 U.S. 824 (1993).  
 8 BIO at 1.  
 9 Gov’t Accounting Office, GAO-09-742, *Information on the Government’s Right to Assert Ownership Control Over Federally Funded Inventions 2* (2009) (hereinafter GAO Report).  
 10 See 126 CONG. REC. 8739 (1980) (statement of Sen. Dole); GAO Report at 2; BIO at 1.  
 11 Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations 2* (1999) (hereinafter COGR).  
 12 H.R. REP. No. 1307 at 1, citing *Science Indicators*, National Science Board at 108-15 (1976).

... the Bayh-Dole Act should provide a “single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.”

Against this backdrop, the Bayh-Dole Act should provide a “single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.”<sup>13</sup>

### Purpose of Bayh-Dole Act

The statutory purpose of the Bayh-Dole Act, set forth in 35 U.S.C. §200, is:

- “to promote the utilization of inventions arising from federally supported research or development;”
- “to promote collaboration between commercial concerns and nonprofit organizations, including universities;” and
- “to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.”<sup>14</sup>

### Statutory Structure

The fundamental change wrought by the Bayh-Dole Act is that, subject to certain requirements, ownership of all federally funded inventions vests in the entity that received the federal funds (such as a university or small business) and not with the inventor or the government.<sup>15</sup> A brief review of the Act makes this clear:

- 35 U.S.C. § 202(a) provides that “Each nonprofit organization or small business firm may . . . elect to retain title to any **subject invention** . . .”
- A “**subject invention**” is “any invention of the **contractor** conceived or first actually reduced to practice in the performance of work under a **funding agreement**.”<sup>16</sup>
- A “**contractor**” is “any person, small business firm, or nonprofit organization that is a party to a **funding agreement**.”<sup>17</sup>
- A “**funding agreement**” is “any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government.”<sup>18</sup>

There are, however, conditions placed on the right of the contractor to retain patent ownership:

- Section 202(a) says the funding agreement may “provide otherwise” if the contractor is not located in the U.S., in exceptional circumstances, when national security or certain nuclear energy programs are involved, and subject to the provisions of § 202(c).
- Section 202(c) outlines other requirements, including:
  - The contractor must disclose the invention to the Federal agency within a “reasonable time” after it becomes known to contractor personnel or the Federal Government may receive title to the invention.<sup>19</sup>
  - The contractor must make a written election that it will retain title to the invention within two years after disclosing the invention to the Federal agency.<sup>20</sup>
  - The Federal agency providing the funding has a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention throughout the world.<sup>21</sup>

<sup>13</sup> *Id.* at 2.

<sup>14</sup> See *Campbell Plastics Eng'ing & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1248 (Fed. Cir. 2004).

<sup>15</sup> 35 U.S.C. §§202, 210.

<sup>16</sup> 35 U.S.C. §201(e).

<sup>17</sup> 35 U.S.C. §201(c).

<sup>18</sup> 35 U.S.C. §201(b). Note, that the Tennessee Valley Authority is excluded from coverage under the Act.

<sup>19</sup> 35 U.S.C. §202(c)(1).

<sup>20</sup> 35 U.S.C. §202(c)(2).

<sup>21</sup> 35 U.S.C. §202(c)(4).

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Speaking about the Bayh-Dole Act in 2005, ex-Senator Bayh said, “I don’t think anybody could have reasonably anticipated the enormity of the chain reaction that followed.”

While proponents of the Act laud the effect of Bayh-Dole as revolutionary others are not so sure – lamenting that the Act “distorts the mission of universities, diverting them from the pursuit of basic knowledge, which is freely disseminated, to a focused search for results that have practical and industrial purposes.”

- In the case of a nonprofit organization, the contractor must share royalties with the inventor<sup>22</sup> and the balance of royalties net of administrative costs, must be used to support scientific research or education.<sup>23</sup>
- Section 203 provides the government with “march in” rights under certain conditions to require the contractor to grant a license to a responsible applicant.<sup>24</sup> The most notable circumstances leading to the exercise of “march in” rights is a failure to achieve practical application of the invention.<sup>25</sup> Note, however, that through mid-2009, federal agencies had never exercised their “march in” rights.<sup>26</sup>
- Finally, Section 202(d) allows the Federal agency to grant an inventor’s request to retain title to the invention if the contractor does not elect to retain title.

### Bayh-Dole in Practice

“The Bayh-Dole Act was designed to facilitate the transfer of publicly funded research to the private sector for further development and commercialization.”<sup>27</sup> Speaking about the Bayh-Dole Act in 2005, ex-Senator Bayh said, “I don’t think anybody could have reasonably anticipated the enormity of the chain reaction that followed.”<sup>28</sup> In 1979, universities received just 264 patents. By 1991, American universities, research institutes and hospitals had filed 1,584 patents applications and negotiated 1,229 licenses, netting \$218 million in royalties. Twelve years later, those same institutions had filed five times as many patent applications, entered into 4,516 licenses, and made over \$1.3 billion in income.<sup>29</sup> All of this resulted in hundreds of new companies<sup>30</sup> and tens of thousands of new jobs annually, especially in the biotechnology sector.<sup>31</sup>

Federal funding of research and development supports this explosive growth. In fiscal year 1980, research and development expenses at universities and colleges totaled slightly more than \$6 billion, with the Federal government contributing over \$4 billion (75%) of the total. By fiscal year 2008, research and development expenditures were nearly \$52 billion, of which more than \$31 billion (60%) was contributed by the federal government.<sup>32</sup>

Undoubtedly, the Act set the stage for university licensing.<sup>33</sup> While proponents of the Act laud the effect of Bayh-Dole as revolutionary<sup>34</sup> others are not so sure – lamenting that the Act “distorts the mission of universities, diverting them from the pursuit of basic knowledge, which is freely disseminated, to a focused search for results that have practical and industrial purposes.”<sup>35</sup>

### Bayh-Dole in the Federal Circuit

The Bayh-Dole Act has received limited play in the Federal Circuit Court of Appeals, being mentioned in only a handful of cases until the recent *Stanford University* case:

- In *Wisconsin Alumni Research Foundation v. Xenon Pharmaceuticals, Inc.*<sup>36</sup> the court concluded it did not have jurisdiction under 28 U.S.C. §1295(a) (“arising under”) in a case just because the Bayh-Dole Act was mentioned in the complaint. Judge Rader dissented to the court’s denial of the petition for rehearing and rehearing *en banc* stating that, “the Bayh-Dole Act, in my view, is most certainly a patent law.”<sup>37</sup>

22 35 U.S.C. §202(c)(7)(B).

23 35 U.S.C. §202(c)(7)(C).

24 35 U.S.C. §203.

25 35 U.S.C. §203(a)(1).

26 GAO Report at 9.

27 BIO at 4.

28 Clifton Leaf, *The Law of Unintended Consequences*, ECONOMIST, Sept. 19, 2005.

29 *Id.*

30 *Id.*

31 BIO at 3.

32 National Science Foundation, *Academic R&D Expenditures: FY 2008* 7, 8 (April 2010).

33 *Univ. of Colo. Foundation, Inc. v. Amer. Cyanamid Co.*, 196 F.3d 1366, 1374 (Fed. Cir. 1999).

34 See BIO.

35 *Intellectual Property: Bayhing for Blood of Doling Out Cash*, ECONOMIST, Dec. 24, 2005

36 252 Fed. Appx. 319, 320 (Fed. Cir. 2007).

37 *Wisc. Alumni Research Foundation v. Xenon Pharm., Inc.*, 263 Fed. Appx. 865, 866 (Fed. Cir. 2008).

## ENHANCING YOUR IP IQ

Vol. III, No.5

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### ABOUT SHB

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- In *University of Rochester v. G.D. Searle & Co*, the court held that the Bayh-Dole Act does not affect the standards of patentability for universities.<sup>38</sup>
- Bayh-Dole was mentioned in passing but was not determinative in the decision in *Madey v. Duke University*, where, more notably, the court discussed the “experimental use defense.”<sup>39</sup>
- In *Campbell Plastics Eng'ing & Mfg., Inc. v. Brownlee*,<sup>40</sup> the court upheld a funding agency's demand for title to an invention when the contractor, Campbell, failed to comply with the disclosure requirements of Bayh-Dole.

### Bayh-Dole at the Supreme Court

Back to today, the Bayh-Dole Act is central to the recent *Stanford University* case. Issues related to that case were first considered by the Federal Circuit Court of Appeals in *Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C.*<sup>41</sup> There, the “contractor” communicated its intent to abandon its interest in the pending patent application. The inventor sought the patent rights, which were granted to him conditioned on his execution of a license to the Federal agency.<sup>42</sup> The inventor admittedly neglected to execute the license.

When the patent issued, the inventor exclusively licensed the plaintiff. Later, the inventor and his assignee sued for infringement and defendant challenged the plaintiffs' standing, relying on Bayh-Dole.<sup>43</sup> Finding that it had jurisdiction, the court noted that the Federal agency had a *discretionary* right to take title to the invention which it had never exercised. Thus, the inventor retained title, and he had standing to sue.<sup>44</sup>

*Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*<sup>45</sup> raises a related issue. The question: Does a researcher/inventor's prior assignment of his rights to a federally funded invention allow him and his assignee to avoid ownership restrictions imposed by the Bayh-Dole Act?<sup>46</sup>

Agreeing with the inventor's assignee, the Federal Circuit said Bayh-Dole does not void prior contract rights, thus setting up Supreme Court review.<sup>47</sup> The outcome of this case may be critical to the future of the Bayh-Dole Act. Whatever the Court's decision, billions of dollars of federally funded research and the patents on resulting inventions are likely to be affected.

### Conclusions

Now that you understand the basics about Bayh-Dole, to keep up-to-date you should:

- Read the Supreme Court's decision in the *Stanford University* case and modify your policies accordingly.
- Make sure you understand the scope and requirements of Bayh-Dole when you work with federally funded research institutions.
- Comply with the requirements of the Bayh-Dole Act to protect your rights.
- Avoid sloppy drafting when preparing agreements with institutions and inventors.
- Closely monitor contracts with federally funded research institutions.
- Avoid commingling private and federal funds on research and development projects if you want to avoid the application of Bayh-Dole.

38 358 F.3d 916, 929 (Fed. Cir. 2004).

39 307 F.3d 1351, 1356 n. 6, 1360-63 (Fed. Cir. 2002).

40 389 F.3d 1243, 1250 (Fed. Cir. 2004).

41 482 F.3d 1347 (Fed. Cir. 2007).

42 *Id.* at 1351.

43 *Id.* at 1351-52.

44 *Id.* at 1352-53, citing *Campbell Plastics Eng'ing & Mfg., Inc.*, 389 F.3d at 1250.

45 583 F.3d 832 (Fed. Cir. 2009), cert. granted, \_\_ U.S. \_\_, 131 S.Ct. 502 (2010).

46 *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, \_\_ U.S. \_\_, 131 S.Ct. 502 (2010).

47 *Board of Trustees of Leland Stanford Junior University*, 583 F.3d at 844.