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# University Technology Transfer - Profit Centers or Black Holes: Moving Toward a More Productive University Innovation Ecosystem Policy

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## University Technology Transfer - Profit Centers or Black Holes: Moving Toward a More Productive University Innovation Ecosystem Policy

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#### Abstract

A great deal has been written over the years commenting on the strengths and weaknesses of the current system by which federal research funding has not produced the ideal results in terms of commercialization of inventions which are developed from such funding. The Bayh-Doyle Act was enacted in an attempt to provide a single uniform national policy which would cut through the government bureaucracy and encourage collaboration between universities and private industry to ensure that federally funded, commercially viable inventions were brought to market in an efficient manner. The question remains however, with the myriad of competing political and economic interests, can any legislation effectively address the myriad of conflicting interests and optimize such a complex system?

This article looks at the various interest groups that provided amicus briefs in the 2011 Supreme Court decision in Stanford v. Roche, which highlights the diverse interests that attempted to weigh in on the case in an effort to ensure that their individual concerns were protected. As is the case with all legislation, it is difficult if not impossible to draw the proper balance between such interest groups when the ultimate objective is to develop a policy which is intended to promote the welfare of society in general, otherwise such optimal results would never be achieved.

This article will provide a brief historical background on how our current policy has evolved over time, focusing on Roche to highlight the competing interests of the members of those organizations that are intimately involved in the research and commercialization process which bring discoveries that lead to inventions that benefit all of mankind. The articles will conclude by arguing that policy changes can and are being made to improve the commercialization process without the need for major legislative reform. What is required however is for collaboration to take place at the university level, with the keen understanding of the competing interests and economic realities particular to the local or regional environment in order to develop well-focused management strategies which form commercialization ecosystems to achieve the desired results. This is not a one size fits all proposition, but a coordinated effort that will take on many different forms depending on the particular university setting.

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#### INTRODUCTION

Beyond an abstract theory of how the Bayh-Dole Act ("the Act")<sup>1</sup> should operate, this article focuses on the practical application and the implications of the Act in our current university system. Having worked closely with university professors and students attempting to commercialize inventions created from research funded by the federal government, it became apparent that universities manage the function in a variety of ways and their success depends on a number of factors. I will begin by providing a brief historical background on how our current technology transfer policy has evolved over time: From the still-existent university framework concerning intellectual property that arose following World War II, to Bayh-Dole's passage in 1980, to the continually evolving ways that universities manage their intellectual property and construct technology transfer policies. The discussion will then highlight the challenges that universities face in managing the process, as illustrated by the United States Supreme Court case *Stanford v. Roche.*<sup>2</sup>

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The discussion will focus on the amicus briefs submitted to the United States Supreme Court in Stanford v. Roche, outlining the competing interests of the members of those organizations that are intimately involved in the research and technology commercialization process which brings socially beneficial inventions to the public, which is the main objective of Bayh-Dole.<sup>3</sup> This article will then conclude by arguing that policy changes at the university level can and are being made to improve the commercialization process without the need for major legislative reform. The diversity of interests illustrated in Stanford creates inefficiencies at the stages where different interest groups become involved. The university, vested with ultimate responsibility over the movement of inventions from laboratory to market,<sup>4</sup> must enact policies that mitigate these inefficiencies. Collaboration among universities, faculty-inventors, and the private sector must take place at the university level, with the keen understanding of the competing interests and economic realities particular to the local or regional environment in order to develop well-focused management strategies which form commercialization ecosystems to achieve the desired results. This is not a one-size-fits-all approach, but a coordinated effort that will take on a variety of forms depending on the particular university setting.

Most (if not all) universities have the potential to *assist* in some stage of bringing a university created invention to market whether as creator, scale-up manufacturer, or commercializer.<sup>5</sup> Failure to commercialize an invention, it is widely believed, results from inefficiencies in the process, which make it economically unfeasible to continue development and ultimately bring the invention to the market. These inefficiencies, as *Stanford* demonstrated, are exposed when competing interests are not properly aligned

<sup>&</sup>lt;sup>1</sup> 35 U.S.C. §§ 200–212 (2000).

<sup>&</sup>lt;sup>2</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., et al., 131 S.Ct. 2188 (2011) [hereinafter *Roche Molecular Sys.*].

<sup>&</sup>lt;sup>3</sup> 35 U.S.C. § 200 (2000).

<sup>&</sup>lt;sup>4</sup> 35 U.S.C. § 201 (c) (2000) (stating that "the term 'contractor' means any . . . nonprofit organization"). Universities make up the majority of nonprofit organizations.

<sup>&</sup>lt;sup>5</sup> U.S. Colleges and Universities–Utility Patent Grants, Calendar Years 1969–2012, USPTO, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/total\_counts/univ\_ct\_list\_2012.htm [http://perma.cc/6S67-FUH9].

and accounted for when creating and administering university policy. Universities and their technology transfer offices ("TTOs") must draft and adopt policies that take into account the diverse interests involved in the commercialization of an invention, through every stage of the process.

#### I. BACKGROUND

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While the origin of patent law in America can be traced all the way back to the United States Constitution,<sup>6</sup> the major influences that shaped patent law to this day generally emerged immediately following World War II.<sup>7</sup> The focus on patent law during this time period was a result of the enormous (and previously unseen) amount of federal spending on research and development to support the war cause.<sup>8</sup>

#### A. Pre-Bayh-Dole

After World War II, the national Patent Planning Commission<sup>9</sup> issued a report in 1945 urging the government to retain a license to use federally funded inventions.<sup>10</sup> A report by the United States Attorney General recommended that the federal government implement a uniform policy to retain title to all inventions developed as a result of federal funding.<sup>11</sup> However, Congress failed to follow such recommendations and passed a multitude of statutes governing title ownership over certain programs or agencies but not others.<sup>12</sup> Agencies not covered by these statutes had broad discretion to adopt an intellectual property policy that best suited them. Some of the best known and most prominent agencies came out on opposite sides of the debate: The Department of Agriculture, Department of Interior, and NASA adopted the Attorney General's "title" approach, while the Department of Defense and the National Science Foundation followed the commission's recommendation and pursued licensing.<sup>13</sup> This lack of uniformity reflected the federal government's uncertainty regarding how intellectual property ownership and rights should be managed. Understandably, this was not reassuring to the private sector interested in investing money in the commercialization of promising inventions. Such a fragmented foundation could not be relied on by investors interested in pursuing an invention for profit, and, as a result. American businesses were spending less private money on research and development than in years past.<sup>14</sup>

The 1960s marked a decade of study regarding America's patent policy, but with little progress or implementation. President Kennedy, in 1963, issued a Memorandum and Policy Statement adopting a middle ground between a licensing policy and a title

<sup>&</sup>lt;sup>6</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>&</sup>lt;sup>7</sup> Rebecca S. Eisenberg, *Public Research & Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1671 (1996).

<sup>&</sup>lt;sup>8</sup> Id.

<sup>&</sup>lt;sup>9</sup> The Commission was created by President Roosevelt in 1941.

<sup>&</sup>lt;sup>10</sup> Eisenberg, *supra* note 7, at 1673.

<sup>&</sup>lt;sup>11</sup> Id.

<sup>&</sup>lt;sup>12</sup> *Id.* at 1676.

<sup>&</sup>lt;sup>13</sup> *Id.* at 1677.

<sup>&</sup>lt;sup>14</sup> Brief Amicus Curiae of Birch Bayh in Support of Petitioner, Stanford v. Roche, 131 S.Ct. 2188 (2011) (No. 09 1159), 2010 WL 5385334.

approach.<sup>15</sup> The memorandum continued to leave enormous discretion to individual agencies in implementing their preferred policy. More importantly, however, the Memorandum requested that the Federal Council for Science and Technology ("FCST") commence annual reporting on the implementation of patent policy by the different agencies, and to recommend changes if necessary.<sup>16</sup> Two years later, FCST established a committee to analyze information on the operation of individual agency patent policy.<sup>17</sup> The Harbridge House study, concluded that commercial utilization of governmentsponsored inventions was very low, regardless of the title owner.<sup>18</sup> Ultimately, however, the authors also concluded that the evidence did not support a finding that either title or nonexclusive licensing was a superior way to promote patent utilization.<sup>19</sup>

Global economic conditions in the 1970s compounded the private sector's frustrations in attempting to commercialize government sponsored inventions. America was facing a recession due, in part, to a reduction in the nation's competitiveness in international markets.<sup>20</sup> While Europe and Asia were emerging as international economic competitors, America faced a slowdown in technological innovation.<sup>21</sup> In 1977, the U.S. trade deficit rose to over \$33 billion.<sup>22</sup> Further, there was a perceived waste of commercialization opportunities of patents owned by the government.<sup>23</sup> Before passage of Bayh-Dole, only five percent of patents owned by the government were being used in the private sector.<sup>24</sup> This was despite the fact that a portion of the government's IP portfolio had been identified as having potential for "further development, application, and marketing."<sup>25</sup> At the time the bill which would become the Bayh-Dole Act was introduced in the Senate, there were twenty-six different agency policies regarding the use of inventions arising from federally funded research.<sup>26</sup>

#### B. The Bayh-Dole Act

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With this in mind, Senators Birch Bayh and Robert Dole introduced a bill in the Senate<sup>27</sup> that focused exclusively on small business and non-profit contractors.<sup>28</sup> Conspicuously absent from the bill was any discussion regarding the rights of large industry contractors. At the time, large industry title rights would continue to be determined by the individual funding agency.<sup>29</sup> The intent of the Bayh-Dole Act was to

<sup>16</sup> *Id.* at 1679. <sup>17</sup> *Id.* 

<sup>22</sup> U.S. Census Bureau, Section on U.S. Int'l Trade in Goods and Servs., U.S. Trade in Goods – Balance of Payments Basis v. Census Basis, www.census.gov/foreign-trade/statistics/historical/goods.pdf [http://perma.cc/VC5B-P7KD].

 $^{3}$  Id.

<sup>24</sup> Wendy H. Schacht, CONG. RESEARCH SERV., RL32076, The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology, 2 (Mar. 16, 2012).

<sup>25</sup> Id. <sup>26</sup> *Id*.

<sup>27</sup> S. 414, 96th Cong. (1980).

<sup>28</sup> Eisenberg, *supra* note 7, at 1691.

<sup>29</sup> Apparently, this was due to the belief of the bill sponsors that to include large businesses "would

<sup>&</sup>lt;sup>15</sup> Eisenberg, *supra* note 7, at 1677.

<sup>&</sup>lt;sup>18</sup> Id. at 1680.

<sup>&</sup>lt;sup>19</sup> Id. at 1681.  $^{20}$  Id.

<sup>&</sup>lt;sup>21</sup> *Id.* at 1685.

create a single, uniform national policy designed to cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.<sup>30</sup>

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The focus on small business participation was also apparent from the language of the Act; the rationale being that small firms tend to be more innovative than larger companies.<sup>31</sup> Several federal agencies conducted research that supported the idea that small, high technology firms are the primary source of significant innovation.<sup>32</sup> A study funded by the Small Business Administration concluded that small businesses were 2.4 times as innovative per employees as large companies.<sup>33</sup> Where large businesses were thought to be risk-averse, predatory, and short-sighted, small businesses were thought of as innovative, efficient, adaptive, and competitive.<sup>34</sup>

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Since its passage, The Act's breadth of governance has been expanded to give large business contractors<sup>35</sup> the same benefits that Congress explicitly provided originally only for small businesses and non-profit institutions. Since its inception, Bayh-Dole has been consistently regarded as a major success in promoting the commercial development of technologies that otherwise would have languished in the government's portfolios.<sup>36</sup>

#### C. Stanford v. Roche

*Stanford v. Roche* did not fundamentally alter the national patent landscape, satisfying the expectation of many patent professionals and experts in academia, industry, and the university.<sup>37</sup> Instead, it reinforced the value of having in place strong contractual agreements between the university and its faculty researchers. However, the real value of *Stanford v. Roche* lies in its ability to serve as a case study for policy makers suggesting the need to make changes to the Bayh-Dole Act.

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At its core, *Stanford v. Roche* was a case where collaboration between a university inventor and a private corporation fulfilled one of the objectives of Bayh-Dole to commercialize a socially beneficial government funded invention. Roche Molecular Systems (previously, Cetus Corporation), through the use of industry-standard contracts,

invite automatic defeat of the bill in response to consumer advocates and antitrust lawyers." *Id.* <sup>30</sup> H.R. REP. NO. 96–1307, pt. 1, at 3 (1980).

<sup>&</sup>lt;sup>31</sup> Schacht, *supra* note 24.

<sup>&</sup>lt;sup>32</sup> *Id.* at 4.

<sup>&</sup>lt;sup>33</sup> NAT'L SCI. BOARD, Science and Engineering Indicators—1993 NAT'L SCI. FOUND. at 185 (1993).

<sup>&</sup>lt;sup>34</sup> Eisenberg, *supra* note 7, at 1696.

<sup>&</sup>lt;sup>35</sup> Via a Memorandum to the Heads of Executive Departments and Agencies, signed in 1983 by President Reagan. *Id.* at 1694–95.

<sup>&</sup>lt;sup>36</sup> See Vicki Loise & Ashley Stevens, *The Bayh-Dole Act Turns 30*, 52 SCI. TRANSL. MED. 2 (2010) (concluding that the Act has helped shape America into an "innovation powerhouse"); see also DAVID LEVENSON, CONSEQUENCES OF THE BAYH-DOLE ACT, *in* MIT Open Courseware (2005) (concluding that the "country has benefited as a whole from the legislation"); see also Gene Quinn, *Bayh-Dole: A Success Beyond Wildest Dreams*, IPWATCHDOG.COM (Sep. 15, 2015),

http://www.ipwatchdog.com/2013/09/15/bayh-dole-a-success-beyond-wildest-dreams/id=45171/ (last visited March 7, 2016).

<sup>&</sup>lt;sup>37</sup> Maddy F. Baer et al., Stanford v. Roche: *Confirming the Basic Patent Law Principle that Inventors Ultimately Have Rights in Their Inventions*, THE BASIC PATENT LAW PRINCIPLE (Mar. 2012), http://www.washington.edu/faculty/files/2014/06/bayhdole\_stanford\_roche2012.pdf [https://perma.cc/89MA-P4BX].

allowed a Stanford University researcher to use the company's proprietary intellectual property (a biotechnology known as Polymerase chain reaction ("PCR")), to develop a new technique for HIV measurement in blood, which resulted in the creation of an HIV testing kit that is now used around the world.<sup>38</sup> Roche was able to develop and begin commercialization while Stanford University was still in the process of filing patent applications for this new measurement technique.<sup>39</sup> The results of Roche's actions are precisely what the sponsors of the Bayh-Dole Act envisioned when drafting and passing this law.<sup>40</sup> The speed and efficiency under which the private sector Roche operated brought the product to market in roughly three years, while the university was attempting to market the invention.

#### 1. Background

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In 1985, a small Silicon Valley biotechnology research company named Cetus Corporation ("Cetus") started developing methods to quantify blood-borne levels of the human immunodeficiency virus (HIV)—the virus that causes AIDS.<sup>41</sup> PCR,<sup>42</sup> a Nobel Prize winning technique developed at Cetus in 1983, was an integral part of the efforts to quantify levels of HIV.<sup>43</sup>

In 1988, in large part due to Cetus's PCR technique, scientists at Stanford University's Department of Infectious Diseases began to collaborate with Cetus scientists to test the efficacy of new AIDS drugs.<sup>44</sup> Dr. Mark Holodniy joined Stanford during this time as a research fellow in the department, and signed a Copyright and Patent Agreement (CPA).<sup>45</sup> Stanford's agreement with Dr. Holodniy, in particular stated that he "'agree[d] to assign' to Stanford his 'right, title, and interest in' inventions resulting from his employment at [Stanford] University."<sup>46</sup>

Dr. Holodniy's research focused on developing an improved method for quantifying HIV levels in patient blood samples, using PCR to measure ribonucleic acid (RNA) from HIV in the blood plasma of infected humans.<sup>47</sup> Because Holodniy was largely unfamiliar with PCR, his supervisor arranged for him to conduct research at

<sup>40</sup> 35 U.S.C. § 200 (2000) (stating that one of the objectives of The Act is to "promote commercialization and public availability.").

<sup>43</sup> Roche Molecular Sys., 131 S. Ct. at 2192.

<sup>44</sup> Id.

<sup>45</sup> *Id.* Such assignments are typically used with scientific personnel at companies and research institutions.

<sup>46</sup> See Stanford University v. Roche Molecular Systems, Inc., AMERICA PINK,

http://america.pink/stanford-university-roche-molecular-systems-inc\_4154005.html (last visited Feb. 24, 2016); *see also* Petition for Writ of Certiorari at 118a–119a, Stanford v. Roche, 131 S.Ct. 2188 (2011) (No. 09-1159) 2010 WL 1138571.

<sup>47</sup> Petition for Writ of Certiorari at 122a–124a, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159).

<sup>&</sup>lt;sup>38</sup> Brief for Respondents at 10–11, Stanford v. Roche, 131 S.Ct. 2188 (2011) (No. 09-1159), 2011 WL 288882.

<sup>&</sup>lt;sup>39</sup> See Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2192 (2011).

<sup>&</sup>lt;sup>41</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2192 (2011).

<sup>&</sup>lt;sup>42</sup> The technique has been widely used in DNA research, forensics, and genetic disease diagnostics. Its inventor, Dr. Kary Mullis, received the Nobel Prize in 1993, the only Nobel Prize ever awarded for research performed at a biotechnology company.

Cetus.<sup>48</sup> In February 1989, Holodniy began regular visits to Cetus over several months to learn PCR and to develop a PCR-based assay for HIV.<sup>49</sup> As a condition of gaining access to Cetus, Holodniy signed a Visitor's Confidentiality Agreement ("VCA").<sup>50</sup> The agreement that he signed stated, "I will assign and do hereby assign" to Cetus any right, title, and interest in each of the ideas, inventions, and improvements made as a consequence of the research access to Cetus.<sup>51</sup>

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Holodniy's research at Cetus and his collaboration with Cetus employees resulted in a PCR-based procedure for calculating the amount of HIV in a patient's blood.<sup>52</sup> This procedure would allow doctors to determine whether a patient was benefitting from a particular HIV therapy.<sup>53</sup> Once this research was concluded, Dr. Holodniy returned to Stanford where he and two other University employees<sup>54</sup> tested the HIV measurement technique. On May 14, 1992, the University filed several patent applications related to the procedure.<sup>55</sup> Because some of the research related to the HIV measurement technique was funded by the National Institutes of Health (NIH)<sup>56</sup>—thereby subjecting the invention to the Bayh-Dole Act-Stanford disclosed the invention to the government, granted the government a nonexclusive, nontransferable, paid-up license to use the patented procedure, and formally notified the NIH that it elected to retain title to the invention.<sup>57</sup> Stanford subsequently secured three patents to the HIV measurement process.<sup>58</sup> Cetus never applied for a patent on the procedure, nor challenged Stanford's application.

In December 1991, Roche purchased Cetus's PCR operations, including Cetus's agreements with Stanford University.<sup>59</sup> After this purchase, Roche began manufacturing and marketing HIV detection kits (based on the measurement technique developed by Holodniy).<sup>60</sup> Stanford later approached Roche, demanding that it take a license to the Stanford patents in which Holodniy was a named inventor, alleging that the Roche product infringed the Stanford patents.<sup>61</sup> Roche refused, indicating that the VCA Holodniy signed with Cetus made Roche, through assignment, a joint owner of the patents with the freedom to practice the patented technology.<sup>62</sup> Stanford disagreed, countering that the inventions were made under federally sponsored research that

<sup>54</sup> Those University employees were Thomas C Merigan and David A. Katzenstein. See Petition for Writ of Certiorari at 33, Roche Molecular Sys., 563 S.Ct. 2188 (No. 09-1159) 2010 WL 1138571. <sup>5</sup> Roche Molecular Sys., 131 S. Ct. at 2192.

<sup>56</sup> *Id.* at 2193.

<sup>57</sup> See 35 U.S.C. § 202 (2000).

<sup>58</sup> U.S. Patent No. 5,968,730 (filed June 6, 1995); U.S. Patent No. 6,503,705 (filed Feb. 13, 2001); U.S. Patent No. 7,129,041 (filed Dec. 16, 2002). All three patents descended from a common parent application.

<sup>59</sup> Brief for Respondents at 10–11, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159) 2011 WL 380825.

<sup>60</sup> Id.

<sup>61</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2193 (2011).

<sup>62</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> Roche Molecular Sys., 131 S. Ct. at 2192.

<sup>&</sup>lt;sup>49</sup> *Id*. <sup>50</sup> Id.

<sup>&</sup>lt;sup>51</sup> Petition for Writ of Certiorari at 122a–124a, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159) 2010 WL 1138571.

<sup>&</sup>lt;sup>52</sup> Roche Molecular Svs., 131 S. Ct. at 2192.

<sup>&</sup>lt;sup>53</sup> *Id.* 

Holodniv had earlier assigned to Stanford, which, under the auspices of the Bayh-Dole Act. Stanford owned.<sup>63</sup>

- 2. District Court Case
- ¶18 In 2005, the Board of Trustees of Leland Stanford Junior University filed suit against Roche Molecular Systems, Inc., alleging that Roche's HIV detection kits were infringing Stanford's three patents.<sup>64</sup> Roche argued that it had acquired the rights to the patents when it purchased Cetus, and pleaded the ownership theory in three forms: (i) as a declaratory judgment counterclaim; (ii) as an affirmative defense; and (iii) as a challenge to Stanford's standing to sue for infringement.<sup>65</sup> The district court held that Roche's counterclaim for ownership of the patents was barred by the California statute of limitation.<sup>66</sup>
- ¶19 Stanford also argued that it had a "right of second refusal" to the patents subject to the Government's right of first refusal, under 35 U.S.C. § 202(d) of the Bayh-Dole Act as described above.<sup>67</sup> The district court agreed with Stanford, holding that Holodniy could only keep title to his inventions "[i]f a contractor does not elect to retain title to a subject invention."68 However, the district court also held that the patent claims were invalid for obviousness.
- ¶20

Both parties appealed.

- 3. Federal Circuit
- The Federal Circuit agreed with the district court that Roche's ownership ¶21 counterclaim was barred by the California statute of limitation, but held that the affirmative defense of ownership was not barred and that "questions of standing can be raised at any time and are not foreclosed by, or subject to, statutes of limitation."<sup>69</sup> The court then determined that Roche had in fact acquired the rights to the three patents due to the agreement that Holodniy had signed with Cetus.<sup>70</sup>
- ¶22

Citing two prior Federal Circuit cases,<sup>71</sup> the court held that the language "agree to assign" in the agreement that Stanford had Holodniy signed was merely a promise to assign his invention rights to Stanford at some undetermined point in the future.<sup>72</sup> Also, when Holodniy signed the contract, Stanford's Administrative Guide to "Inventions, Patents, and Licensing" stated that: "[u]nlike industry and many other universities, Stanford's invention rights policy allows all rights to remain with the inventor if

<sup>&</sup>lt;sup>63</sup> Roche Molecular Sys., 131 S. Ct. at 2193.

<sup>&</sup>lt;sup>64</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 487 F. Supp. 2d 1099, 1111, 1115 (N.D. Cal. 2007).

<sup>&</sup>lt;sup>65</sup> Id

<sup>66</sup> Id. at 1117.

<sup>&</sup>lt;sup>67</sup> Id. (citing 35 U.S.C. § 202(d)).

<sup>&</sup>lt;sup>68</sup> *Id.* at 1118.

<sup>&</sup>lt;sup>69</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 583 F.3d 832, 837 (Fed. Cir. 2009). <sup>70</sup> *Id.* at 842.

<sup>&</sup>lt;sup>71</sup> Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1253 (Fed. Cir. 2000); FilmTec Corp. v. Allied–Signal, Inc., 939 F.2d 1568, 1572–73 (Fed. Cir. 1991). <sup>72</sup> Roche Molecular Sys., 583 F.3d at 842.

possible."<sup>73</sup> With respect to the Cetus contract, the Federal Circuit interpreted the contract language "do hereby assign" to be "a present assignment of Holodniy's future inventions to Cetus," thereby giving Cetus immediate rights in Holodniy's future inventions.<sup>74</sup> By the time Holodniy executed an assignment to Stanford three years later with respect to the patent applications that Stanford filed, his rights had already transferred to Cetus and the subsequent assignment was void.<sup>75</sup>

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The Federal Circuit found that Stanford itself received constructive notice of Cetus's ownership rights at least through Holodniy's employment by Stanford—in other words, Holodniy's knowledge of the Cetus agreement was imputed to his employer.<sup>76</sup> The Court also found that Stanford had similar constructive notice through Holodniy's supervisor, who directed Holodniy to work with Cetus and executed agreements of his own that transferred intellectual property rights to Cetus.<sup>77</sup> Although Stanford asserted that Holodniy signed the agreement with Cetus solely on his own behalf and not Stanford's, the Court found that this argument missed the point.<sup>78</sup> According to the Federal Circuit, the agreement with Cetus indicates that Holodniv was acting as an independent contractor with respect to Cetus, not with respect to Stanford, and that "Holodniy [had] signed away his individual rights as an inventor, not Stanford's."<sup>79</sup>

With respect to Stanford's claims about the Bayh-Dole Act, the Federal Circuit overruled the district court's decision, holding that the Act does not void an otherwise valid prior transfer of rights.<sup>80</sup> As a result, Stanford was entitled to only those rights that remained after the Government declined to exercise its option.<sup>81</sup>

According to the Federal Circuit, Stanford therefore lacked standing to sue Roche, the district court lacked jurisdiction over Stanford's infringement claim, and the district court should not have addressed the validity of the patents. Accordingly, the Court vacated the district court's finding of invalidity and remanded the case for dismissal due to lack of standing.<sup>82</sup> Stanford appealed to the Supreme Court based on its argument that Bayh-Dole overrides normal ownership of inventions.

4. United States Supreme Court

¶26 In November 2010, the Supreme Court agreed to hear the case. The case was decided on June 6, 2011. The decision was "largely moot" as the majority, led by Chief Justice Roberts, held that U.S. patents have always (since 1790) initially vested in "the inventor" and that the non-specific language of the Bayh-Dole Act does nothing to change the original framework.<sup>83</sup>

<sup>73</sup> *Id.* at 841.

- <sup>80</sup> *Id*.
- <sup>81</sup> Id.
- <sup>82</sup> *Id.* at 848.

<sup>83</sup> Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2192 (2011).

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<sup>&</sup>lt;sup>74</sup> *Id*. <sup>75</sup> *Id.* at 842.

<sup>&</sup>lt;sup>76</sup> *Id.* at 843. <sup>77</sup> *Id.* 

<sup>&</sup>lt;sup>78</sup> *Id.* at 844.

<sup>&</sup>lt;sup>79</sup> *Id*.

¶27 The effects on patent law were negligible. The Supreme Court's grant of certiorari for this case came as a surprise to many intellectual property attorneys who did not believe that the Bayh-Dole Act changed the centuries old proposition that inventors ultimately have rights in their patents.<sup>84</sup> As a result, the Supreme Court's decision reassured inventors, as well as all those involved in the practice of intellectual property law, that their longstanding belief that ownership rights in inventions belong first and foremost to inventors is correct.

#### II. AMICUS BRIEFS

**Stanford v. Roche** highlighted the competing interests that have shaped the application of Bayh-Dole. Through their amicus briefs, industry organizations, private individuals, intellectual property owner groups, technology transfer managers, and universities weighed in on the then-future outcome of this case. Their briefs demonstrated a diverse and often divergent range of interests that each group actively tried to account for under the Bayh-Dole framework. The process of reforming university policy to satisfy all of these interests will require concessions and flexibility from all parties. However, when this is achieved, Bayh-Dole will effectively govern the technology transfer policies of our nation's universities, satisfying its objective of commercializing socially beneficial discoveries for the public in a way that rewards the university, inventor, and private industry, while simultaneously protecting the investment of the federal government and the public.

#### A. Private Industry

The interest groups writing on behalf of private industry strongly support collaboration between business and university research departments. Academic licensing has, over 15 years of available data, contributed between \$86 billion and \$388 billion per year (in 2005 dollars) to the gross domestic product, and total number of "person years of employment" range from 900,000 to 3 million over the same time period.<sup>85</sup> The transfer of technology between industry and academia is a major focus of these interest groups, and is central to the industry output and job creation in America.<sup>86</sup>

Eli Lily and others argue that a tremendous amount of money is invested in the research and development of new technologies, and a clear framework of patent title and assignability is central to off-setting some of that risk.<sup>87</sup> Even after enormous amounts of energy and capital are invested in a single product such as a biopharmaceutical medicine, it is estimated that there is still only a one in 5,000 chance that the medicine will make it

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<sup>&</sup>lt;sup>84</sup> See Maddy F. Baer et al., Stanford v. Roche: Confirming the Basic Patent Law Principle That Inventors Ultimately Have Rights in Their Inventions, LES NOUVELLES 19 (Mar. 2012), http://www.washington.edu/faculty/files/2014/06/bayhdole stanford roche2012.pdf.

<sup>&</sup>lt;sup>185</sup> The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2010, BIOTECHNOLOGY INDUSTRY ORG., http://www.bio.org/articles/economic-contribution-universitynonprofitinventions-united-states-1996-2010 (last updated June 20, 2012) [https://perma.cc/3EZ5-2PZZ]. <sup>86</sup> Id.

 <sup>&</sup>lt;sup>86</sup> Id.
 <sup>87</sup> See Brief of Intel Corporation, Eli Lilly, and Company, Johnson & Johnson, Life Technologies
 Corporation, Pfizer Inc., and Sap America, Inc. as Amici Curiae in Support of Respondents 9–11, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159).

from the lab to the market.<sup>88</sup> For this reason, Eli Lily has a keen interest in reducing its risk whenever possible.

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Large pharmaceutical companies, in order to promote collaboration with nonprofit research institutions, rely on surety of title. To own a patent outright one day, then the next day (or many years down the road) have it taken away through no act or fault of the company will stifle any desire that private industry has to collaborate. It is especially troubling for private industry if a university were to recognize the enormous value in a discovery, hire the researcher, and then disingenuously sprinkle the research with federal funds for the sole purpose of invoking Bayh-Dole.<sup>89</sup> For obvious reasons, this scenario would halt collaboration between private industry and non-profits.

#### B. Public

Prior to Bayh-Dole's passage, about \$75 billion of taxpayer money was being invested into government-sponsored research & development each year.<sup>90</sup> The United States' patent portfolio was estimated to contain around 28,000 patents; yet fewer than five percent of them were being commercially licensed.<sup>91</sup> Today, the United States remains a major supporter of technological innovation and research.<sup>92</sup> More than half of the scientific and technical research conducted at the university level is funded by federal grants.<sup>93</sup>

<sup>¶33</sup> The public-at-large was represented in a number of briefs authored by the United States, BayhDole25, a nonprofit organization,<sup>94</sup> and even former Senator and author of the bill, Birch Bayh. The principle interest that these groups sought to further (on behalf of the American public) was the efficient use of tax dollars to get beneficial inventions back into the hands of the American people. To this end, the interest groups voice major concern with the prospect of the public "double paying" for an invention.<sup>95</sup> That is, the public essentially is paying twice for the same invention when a private firm holds an exclusive right to an invention that has been generated using federal funding—initially through the taxes to support the research that produced the invention, then again through royalty costs being recouped by the company via monopoly pricing when the product hits the market.<sup>96</sup> The broad issue can be framed as "the public paying once and getting nothing, or paying twice and getting the innovation."<sup>97</sup>

<sup>&</sup>lt;sup>88</sup> See Joseph A. Di Masi & Henry G. Grabowski, *The Cost of Biopharmaceutical R & D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 475 (2007).

<sup>&</sup>lt;sup>89</sup> Id.

<sup>&</sup>lt;sup>90</sup> Bayh-Dole Act-History, WIKIPEDIA, http://en.wikipedia.org/wiki/Bayh-Dole\_Act (last viewed July 30, 2013) [https://perma.cc/4SYG-SAYN].

<sup>&</sup>lt;sup>21</sup> Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 94 (2004).

<sup>&</sup>lt;sup>92</sup> Brief for the United States as Amicus Curiae, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09 1159), 2010 WL 3777203.

<sup>&</sup>lt;sup>93</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GA0-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 1 (2009).

<sup>&</sup>lt;sup>94</sup> "BayhDole25 is a non-profit that advocates for preserving the value of the BayhDole Act." BAYHDOLE25.ORG, www.bayhdole25.org [https://perma.cc/R4SM-YG6E] (last visited Feb. 12, 2016).

<sup>&</sup>lt;sup>95</sup> Gary Pulsinelli, Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh–Dole Act, 7 MINN, J. L. SCI. & TECH. 393, 443 (2006).

<sup>&</sup>lt;sup>96</sup> Eisenberg, *supra* note 7, at 1666.

<sup>&</sup>lt;sup>97</sup> Pulsinelli, *supra* note 95, at 443.

#### C. Universities

<sup>¶34</sup> Universities now stand at a crossroads due to Bayh-Dole; they currently have an affirmative duty to take steps to bring socially beneficial intellectual property to the public,<sup>98</sup> while preserving their historical mission of producing and preserving public knowledge.<sup>99</sup>

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The current university policy model defines one of the goals of a publicly subsidized research university as research in basic science.<sup>100</sup> Basic science describes natural phenomena and foundational principles of the world, and is inherently noncommercial.<sup>101</sup> This charge is a remnant of institutional policy-makers immediately following World War II,<sup>102</sup> and demands reconsideration. Basic scientific research has evolved dramatically and there is no longer a clear delineation between basic science and applied science (applied science has historically been considered to be the interest of the engineering departments, and commercial in nature<sup>103</sup>).<sup>104</sup> This basic research focus is not only perpetuated by social expectations and the policy-makers themselves, but also by the federal government's actions to maintain this pursuit.<sup>105</sup> Tax regulators and funding agencies expect universities to perform public, noncommercial research.<sup>106</sup> A university's tax-exempt status is dependent upon, among other things, its noncommercial research goals.<sup>107</sup> Further, legal restrictions have been imposed on the amount of space that universities are allowed to devote to research that is commercial in nature.<sup>108</sup> Even private universities have construed their mission as one that excludes productdevelopment activities.<sup>109</sup>

#### D. Inventors

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The interest groups representing the inventors and private owners of intellectual property view their members as serving a critical societal function by the research they conduct, and acknowledge that their responsibility is primarily to the public.<sup>110</sup> The research produced at our nation's institutions continues to be recognized as central to our democracy, and conducted with the purpose of supporting the common good.<sup>111</sup> The United States Supreme Court has repeatedly been committed to the idea that faculty and

<sup>100</sup> Id. at 1957.
<sup>101</sup> Id.
<sup>102</sup> Id.
<sup>103</sup> Id. at 1977.
<sup>104</sup> Id. at 1974.
<sup>105</sup> Id. at 1960.
<sup>106</sup> Id.
<sup>107</sup> Id.
<sup>108</sup> Id.
<sup>109</sup> Id. at 1961.

<sup>&</sup>lt;sup>98</sup> 35 U.S.C. § 200 (2000).

<sup>&</sup>lt;sup>99</sup> See Liza Vertinsky, Universities as Guardians of Their Inventions, 4 UTAH L. REV. 1949, 1981–82 (2012).

<sup>&</sup>lt;sup>110</sup> AM. ASS'N U. PROFESSORS POLICIES AND REPORTS, 1915 DECLARATION OF PRINCIPLES ON ACADEMIC FREEDOM AND TENURE, *available at:* http://www.aaup.org/report/1915-declaration-principlesacademic-freedom-and-academic-tenure (last visited July 30, 2013) [https://perma.cc/53AV-8G37].

<sup>&</sup>lt;sup>111</sup> Brief of American Association of University Professors, IEEE-USA, and IP Advocate as Amici Curiae in Support of Affirmance at 11, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159).

academic professionals are the keystones to the perpetuation of freedom through the training of the nation's youth.<sup>112</sup>

Inventors employed by a university generally wish to retain title to the fruits of ¶37 their labor so that they have the power to contractually assign those rights away in exchange for royalties. Allowing a contractor, by obtaining federal funding, to eliminate rights acquired by a third party is contrary to the intent of Bayh-Dole, according to the authors.<sup>113</sup>

The inventor groups maintain that The Act first and foremost establishes a "regulated contracting regime" that operates within the federal contract and procurement system.<sup>114</sup> Under this scheme, the title rights of each party can be determined by the federal funding agreements (pursuant to Bayh-Dole § 202(c))<sup>115</sup> between the federal agency and the federal contractor and the assignment agreements between the inventor(s) and federal contractor.<sup>116</sup> The act requires not that the university automatically be given title when federal funds are used, but rather that the university secures invention title and patent rights through contract.<sup>117</sup>

A major concern is that basic research is becoming less of a focus for private industry.<sup>118</sup> While the United States leads the world in patent outputs, China now leads the world in bringing "high technology" to the marketplace.<sup>119</sup> Further, the "high impact" journals based in the United States are becoming filled with articles that originate outside of this country.<sup>120</sup> The IEEE is concerned that American business focus on commercialization of technology is swallowing up the desire to be the most technologically innovative country.<sup>121</sup> That is, the private sector is seeking a more streamlined approach to supply chains and commercialization of products at the expense of actually creating the ground-breaking innovations which underlie the system.<sup>122</sup>

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Another major threat to nonprofit/industry collaboration, according to the inventor groups, is the concern that a university will superficially sprinkle an invention with federal funds, thus taking title away from the private company.<sup>123</sup> This concern is seemingly validated because the Bayh-Dole Act applies to inventions that are conceived *or* first reduced to practice in the performance of work using federal funds.<sup>124</sup> That is, even if an invention is first conceived by an inventor working for a private company using no government funding, the university could still acquire ownership of the invention if it was first actually reduced to practice under the funding agreement.<sup>125</sup> Even if the inventor/private company already filed a patent application, this is only a

<sup>114</sup> *Id.* at 3.

- <sup>119</sup> *Id*.
- <sup>120</sup> *Id*. <sup>121</sup> *Id*.
- $^{122}$  *Id*.

<sup>&</sup>lt;sup>112</sup> See Sweezy v. New Hampshire, 354 U.S. 234, 250 (1957); see also Keyishian v. Bd. of Regents, 385 U.S. 589, 603 (1967). <sup>113</sup> Brief, *supra* note 111, at 7.

<sup>&</sup>lt;sup>115</sup> 35 U.S.C. § 202(c) (2000).

<sup>&</sup>lt;sup>116</sup> Brief, *supra* note 111, at 3.

<sup>&</sup>lt;sup>117</sup> *Id.* at 4.

<sup>&</sup>lt;sup>118</sup> Brief. *supra* note 111. at 3.

<sup>&</sup>lt;sup>123</sup> Brief, *supra* note 87, at 7.

<sup>&</sup>lt;sup>124</sup> 35 U.S.C. § 201(e) (2000).

<sup>&</sup>lt;sup>125</sup> Brief, *supra* note 87, at 20.

constructive reduction to practice, not an actual reduction as required by the Act.<sup>126</sup> By vesting title automatically with the inventor, and subsequently allowing them to assign the rights as they see fit, there is no concern of a federal contractor acquiring title to an invention that a private company does not intend on dispensing.

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Transparency among the interested parties, according to the inventor groups, allows for proper balance of interests and rights between the university and faculty. Recognizing the co-dependent nature of the academic relationship, there should not be attempts to hide information or usurp the rights of one another. Rather, faculty should be informed of the specifics in any intellectual property agreements that they sign with the university.<sup>127</sup> Relatedly, faculty should be expected to uphold their end of the bargain regarding intellectual property discoveries and not attempt to undermine or go around the university's contractual rights.

#### E. Federal Government

The federal government sought to protect its own interest in intellectual property<sup>128</sup> by arguing that (in most cases) title rights vest automatically in the contractor.<sup>129</sup> From here, the contractor may elect to retain title.<sup>130</sup> If the contractor declines to retain title or fails to comply with his statutory duties under the act, the government funding agency may step in and take title.<sup>131</sup> Only after the agency has taken title does the inventor even have the potential to exercise any rights in the invention—if the federal agency decides to affirmatively grant the inventor's request for rights.<sup>132</sup>

Under this interpretation of Bayh-Dole, a specific hierarchy emerges: at the top of ¶43 the ladder is the contractor who initially has title; next, the U.S. government, who can gain title under a variety of scenarios, but mainly, if the contractor elects not to retain title; and lastly, the inventor, whose rights in the invention are only created if the contractor fails to retain title and the government elects, after consultation with the contractor, to give title to the inventor.<sup>133</sup> This chain of command appears dubious if efficient commercialization is one of the main objectives of Bayh-Dole.<sup>134</sup> It would seem that the government is substituting efficiency in commercialization for its own title security in inventions. That is, even if the inventor wanted to further a discovery and both the university and the U.S. agency had no interest in doing so, there would either be a lengthy delay as the inventor waited for the title to pass from the university to the agency, then waited again for the agency to consult with the contractor before passing title to the inventor, or the agency could choose not to pass title to the inventor at all. The inventor, who may be the most capable of making the invention marketable, is, under the United States' argument, the least capable of actually getting title.<sup>135</sup>

<sup>&</sup>lt;sup>126</sup> Id.

 $<sup>^{127}</sup>$  *Id.* at 5–6.

<sup>&</sup>lt;sup>128</sup> 35 U.S.C. § 200 (2000).

<sup>&</sup>lt;sup>129</sup> Brief, *supra* note 92, at 5.

<sup>&</sup>lt;sup>130</sup> 35 U.S.C. § 202(a) (2000).

<sup>&</sup>lt;sup>131</sup> *Id*.

<sup>&</sup>lt;sup>132</sup> 35 U.S.C. § 202(d) (2000).

<sup>&</sup>lt;sup>133</sup> Brief, *supra* note 92, at 13.

<sup>&</sup>lt;sup>134</sup> 35 U.S.C. § 200 (2000).

<sup>&</sup>lt;sup>135</sup> See Brief, supra note 92, at 13.

- ¶44 On the other hand, commercialization may be best served when title passes from the contractor to the government, instead of vesting immediately in the inventor or passing from the contractor to the inventor. Both inventors and nonprofits face the challenge of balancing profit motive with the desire to benefit the public. Universities and other nonprofits should, in theory, be less susceptible to this conflict than individual inventors. However, as discussed in other briefs, this is becoming less and less of the case. Regardless, there is fear that an inventor with title could shop the discovery for the largest payout, not necessarily the best prospect for commercial success.<sup>136</sup> While it would seem that these two considerations are inseparable, this is not always the case. Patent trolls purchase intellectual property for the sole reason of suing others for patent infringement.<sup>137</sup> There is nothing barring an inventor from selling title to a key invention to one of these firms, who would do nothing useful or beneficial with it. For this reason, it may be a good thing that the government is an intermediary between the contractor and the inventor. The government, once it has taken title to an invention, has the power to grant exclusive or partially exclusive licenses, but only under certain conditions.<sup>138</sup> A license can only be granted when it is a "reasonable and necessary incentive to . . . promote the invention's utilization by the public."<sup>139</sup> Further, the licensee must make a commitment to achieve practical application of the invention.<sup>140</sup>
- On the one hand, an inventor, if vested with title either initially or following the **¶45** contractor's surrender, would likely be best situated to pursue the invention through the various development stages, both because of their intimate knowledge of the invention and because of their self-interest in capitalizing on its success. On the other hand, the government has an interest in the property that arises from their investment of federal funds. Further, there is concern that an inventor may put profit before the public interest and sell their title to the highest bidder rather than the one best situated to bring the invention to market. The government, on the contrary, is only able to license the invention when it would promote the public interest and the licensee has made a commitment to commercialize the product.

#### F. Venture Capital

Venture capital is a subset of private equity, typically coming from high net worth individuals or venture capital firms.<sup>141</sup> Investors provide capital to new and emerging **¶46** businesses with perceived long-term growth potential.<sup>142</sup> Generally, these start-up businesses are unable to secure financing through traditional means (i.e. banks or public markets) due to their assets, size, and stage of development, and so they must turn to venture capital firms for their funding needs.<sup>143</sup> Venture capital investments are often made in exchange for equity in the company (as opposed to debt) as well as an active role

<sup>&</sup>lt;sup>136</sup> Ted Sichelman, Commercializing Patents, 62 STAN. L. REV. 341, 368 (2010).

<sup>&</sup>lt;sup>137</sup> Id

<sup>&</sup>lt;sup>138</sup> 35 U.S.C. § 209(a) (2000).

<sup>&</sup>lt;sup>139</sup> *Id.* at § 209(a)(1).

<sup>&</sup>lt;sup>140</sup> *Id.* at § 209(a)(2).

<sup>&</sup>lt;sup>141</sup> Understanding Venture Capital, U.S. SMALL BUS. ADMIN., http://www.sba.gov/content/venturecapital [https://perma.cc/5LDO-C5YA].

 $<sup>^{142}</sup>$  Id.  $^{143}$  Id.

in the company's operations.<sup>144</sup> These equity investments are crucial because lenders generally will not lend to a business without a substantial equity cushion or collateral.<sup>145</sup> After injections of venture capital, these start-ups are able to more rapidly leverage themselves and grow. Due to the risk associated with investing in a start-up, investors often require a higher rate of return on the money than a traditional lender.<sup>146</sup>

This form of capital is essential for new and emerging businesses in high technology industries such as Information Technology, Medical/Health/Life Science, and Non-High Technology.<sup>147</sup> Eleven percent of private sector jobs come from venturebacked companies and venture backed revenue accounts for 21% of America's Gross Domestic Product.<sup>148</sup> In 2012, \$4.1 billion was invested in biotechnology (like Cetus's polymerase chain reaction (PCR) technique) alone.<sup>149</sup> In total, nearly \$6.7 billion in venture capital was invested in these early-stage, high risk start-up companies.<sup>150</sup>

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The author of this amicus brief, the National Venture Capital Association (NVCA), "advocates for public policies that encourage innovation, spur job creation, and reward long-term investment in start-up companies.<sup>3151</sup> As the major trade group for venture capitalists, NVCA speaks on behalf of over 400 members, including the many of the largest venture capital firms in the nation.<sup>152</sup> NVCA members invest in a wide array of industries: biotechnology, semiconductors, health care, and telecommunications, to name a few.<sup>153</sup> Accordingly, the NVCA is intimately familiar with the effects that the Bayh-Dole Act has on intellectual property in a given industry, and how this guides their investment strategies.<sup>154</sup>

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At the heart of the NVCA's interest in *Stanford v. Roche* and the Bayh-Dole Act is rate of return. This proposition should be readily apparent from the outset, given the nature of venture capital and its use as a vehicle for investment. However, for money to be made and returns paid to investors, the venture capital industry relies on the intelligent allocation of risk. Risk would be most efficiently allocated when operating under a clear framework of ownership rights in the inventions that the venture capital firms would be investing in. The NVCA argues that reversal of the Federal Circuit's opinion would restore Bayh-Dole's central goal of a "straight forward and predictable ownership framework" of intellectual property created by non-profits and universities through

<sup>151</sup> NVCA Policy Overview, NATIONAL VENTURE CAP. ASS'N., http://www.nvca.org/index.php?option=com content&view=article&id=320&Itemid=585

[https://perma.cc/M7K6-4NK8].

<sup>&</sup>lt;sup>144</sup> Id.

<sup>145</sup> *Id.* 

 $<sup>^{146}</sup>$  *Id*.

<sup>&</sup>lt;sup>147</sup>See Bobby Franklin, et. al., 2015 National Venture Capital Association Yearbook 12 (2015).

<sup>&</sup>lt;sup>148</sup> Mark Heesen, Venture Impact: The Economic Importance of Venture Capital-Backed Companies to the U.S. Economy 2-3 (2011)...

<sup>&</sup>lt;sup>149</sup> VC Investments O1 '13 – MoneyTree – National Data, NATIONAL VENTURE CAP. ASS'N, http://www.nvca.org/index.php?option=com content&view=article&id=344&Itemid=103 [https://perma.cc/GG2L-EZBR].

 $<sup>^{150}</sup>$  Id.

<sup>&</sup>lt;sup>152</sup> Mission and Core Values, NATIONALL VENTURE CAP. ASS'N., http://www.nvca.org/index.php?option=com\_content&view=article&id=339&Itemid=653 [https://perma.cc/5WRJ-BMAG].

<sup>&</sup>lt;sup>153</sup> Brief of the National Venture Cap. Ass'n as Amicus Curiae in Support of Petitioner, Stanford v. Roche, 563 U.S. 776 (2011) (No. 09-1159), at 1. <sup>154</sup> *Id.* at 3.

federal funding.<sup>155</sup> Thus predictability of ownership is the key concern of those who invest in the commercialization of technology.

#### **III. DISCUSSION**

¶50 Some universities possess the resources to see an invention all the way from discovery to marketplace, while others may seek to sell the rights to the invention to a third party as quickly as possible. What generally exists today is a race from discovery to commercialization with the university obtaining as much control over the invention as they can. This is not necessarily the most effective way to move inventions to the public, and not conducive to an environment envisioned by the drafters of Bayh-Dole. Universities must be able to self-evaluate their ability to control intellectual property, and then act accordingly, pursuant to that determination. If they are aware that they do not have the private investments available to fund commercialization themselves, then they should perhaps sell the IP rights quickly after discovery. If their technology transfer office is understaffed or undermanaged, perhaps a license back to the inventor is the best way to speed development. Unfortunately, the approach taken by many universities (usually those least able to fund their discoveries) is that it's better to let an invention laywaste while trying to commercialize it rather than identifying a more suitable commercializer early on and relinquishing their rights.

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This is not a moral condemnation of those universities not equipped to manage the entire commercialization process; rather, it should be motivation to move discoveries into the hands of more capable managers to ensure commercialization while also benefiting from royalties paid on the licenses. On the other hand, while the major research universities may be capable of overseeing the entire process, policy changes may need to be implemented in those institutions to ensure that the objectives of Bayh-Dole remain the motivation behind their actions (it is unlikely that Bayh-Dole contemplated the possibility of MIT, by virtue of their licenses and commercialization, becoming the 11<sup>th</sup> largest economy in the world, if they were to form a nation today).

#### A. Universities as Commercializers

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When Bayh-Dole was passed into law in 1980, it transferred the responsibility for optimizing socially beneficial inventions from the federal government to universities. As a result, universities are in a far superior position to promote an economic ecosystem that generates economic benefits to the university and inventor, and also economic growth potential to the private sector and the economy in general. Many universities (in fact, most) do not have the economic capability, manpower, access to venture capital, nor desire to tend to an invention all the way from discovery to commercialization. As Timothy L. Faley and Michael Sharer put it, "universities are not commercializers."<sup>156</sup>

153 However, some universities do support impressive commercialization efforts. A 2010 survey by the Association of University Technology Managers (AUTM) determined

<sup>&</sup>lt;sup>155</sup> *Id.* at 4.

<sup>&</sup>lt;sup>156</sup> Timothy L. Faley & Michael Sharer, *Technology Transfer and Innovation: Reexamining and Broadening the Perspective of the Transfer of Discoveries Resulting from Government-Sponsored Research*, 3 COMP. TECH. TRANSFER AND INNOVATION 109, 126 (2005).

that since Bayh-Dole's passage in 1980, more than 8,107 new businesses have been created to commercialize academic discoveries.<sup>157</sup> The reason that universities are credited for commercialization when these new businesses are created is because these start-ups are most often headed by the faculty researcher associated with the discovery. In some instances, research assistants and technicians working under the principal investigator (faculty researcher) may also be invited to join the start-up business and assist in further development.

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These are scenarios where the university effectively and efficiently manages an invention all the way to commercialization. Some universities are in a position to achieve this. Wendy Schacht, in her Congressional Research Service report, indicates that the vast majority of start-up businesses created to manage university discoveries are associated with just seven schools: MIT, The University of California, California Tech, The University of Minnesota, Johns Hopkins University, The University of Utah, and The University of Virginia.<sup>158</sup> These universities undoubtedly possess all the characteristics that are needed to create a productive innovation ecosystem. A 2009 report concluded that MIT graduates, faculty, and staff have founded 25,800 active companies, employing over 3 million people and generating \$2 trillion in annual revenue.<sup>159</sup> Another study indicates that the University of California system generates \$91 million in net licensing income each year.<sup>160</sup>

1. Recognizing the Dual Nature of Scientific Research

Scientific discoveries have increasingly become more dual-natured.<sup>161</sup> Patentable inventions have been created both as inputs into further discovery and as an invention with immediate commercial application.<sup>162</sup> To halt the perpetuation of basic research</sup> being the sole goal of university research and to reform the mission of research universities to include research in innovations that are both basic and applied, the changing nature of science and technology needs to be accounted for.

Due to the failure to adapt as scientific research becomes more dual-natured, governmental funding of research often ends at the completion of the discovery phase.<sup>163</sup> Because of this premature withdrawal, funding sources such as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have formed to support later stages of research and to bridge the gap between research and development.<sup>164</sup> However, financial support from these programs has paled in comparison to the support received from federal agencies.<sup>165</sup> Where the NIH alone had a

<sup>&</sup>lt;sup>157</sup> Schacht, *supra* note 24, at 16..

<sup>&</sup>lt;sup>158</sup> Schacht, *supra* note 24, at 10.

<sup>&</sup>lt;sup>159</sup> Edward B. Roberts & Charles Eesley, Entrepreneurial Impact: The Role of MIT 8 (Feb. 2009), available at

https://entrepreneurship.mit.edu/sites/default/files/documents/ExecSummary Entrepreneurial Impact The Role of MIT.pdf [https://perma.cc/78AP-KTVY].

<sup>&</sup>lt;sup>160</sup> Schacht, *supra* note 24, at 10.

<sup>&</sup>lt;sup>161</sup> *Id.* at 1976.

 $<sup>^{162}</sup>$  *Id*.

<sup>&</sup>lt;sup>163</sup> *Id.* at 1957.

 $<sup>^{164}</sup>$  *Id.* at 1957.  $^{165}$  *Id.* 

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budget of over \$30.9 billion in 2011, with 80% being given to research institutions,<sup>166</sup> the SBIR and STTR programs had only \$2.4 billion that year, with a total of \$32.9 billion awarded since its inception in 1983.<sup>167</sup>

To acknowledge the practical application of scientific research and further assist an invention towards commercialization, public funding needs to be extended beyond the discovery phase. Such funding would provide the university inventors with the resources necessary to further develop their inventions beyond the time when an innovation is disclosed. When this happens, private investors are more likely to invest, because their risk is lessened when the invention is beyond its embryonic stage, where the efficacy of the invention may not be apparent and the chances of commercial success or failure are hardest to measure.<sup>168</sup> Furthermore, the basic research that the further-developed invention is predicated on would remain in the public domain for a longer period of time, allowing society to benefit from the different applications that can arise from a single basic discovery. Under the old model, universities had to rush out and patent any new discoveries because, lacking the resources to develop it, they had to lay their claim in the intellectual property so they could license it. Otherwise, they would be stuck holding basic research while also applying it to the prospective innovations that they see fit.

#### 2. Retention of Tacit Information

Another barrier to commercialization is the challenge associated with sharing tacit knowledge in the face of dealing with business professionals lacking in-depth technical knowledge.<sup>169</sup> The development process is more likely to require this exchange of information between the university and private industry.<sup>170</sup> Continued inventor engagement downstream is almost always necessary for the successful commercialization of an invention.<sup>171</sup> However, in many cases, a university researcher is happy being just that—a researcher. As a basic discovery snowballs into a large commercially focused project, many academics return to basic research. To be certain, some inventors are commercially driven from the start. However, a great many are content just doing research without working with a commercializer. Unfortunately, the tacit knowledge associated with a particular discovery is often central to that discovery's commercial success.<sup>172</sup> The inventor and his or her team are intimately familiar with their particular innovation, and thus possess not only the specialized knowledge of how the innovation functions conceptually, but also how their particular innovation would succeed in the marketplace.

<sup>&</sup>lt;sup>166</sup> About NIH-Budget, NAT'L INST. HEALTH, (Oct. 14, 2015), http://www.nih.gov/about/budget.htm [https://perma.cc/LF6B-FQVW].

<sup>&</sup>lt;sup>167</sup>*Awards-Number of Awards by Year*, SBIR/STTR, http://sba-sbir-uat.reisys.com/past-awards [https://perma.cc/QH6T-TEFQ]. For easier access to the data, open the excel spreadsheet to the top right of the bar graph. *Id*.

<sup>&</sup>lt;sup>168</sup> Vertinsky, *supra* note 99, at 1993.

<sup>&</sup>lt;sup>169</sup> *Id.* at 1979.

<sup>&</sup>lt;sup>170</sup> *Id*.

 $<sup>^{171}</sup>$  *Id*.

<sup>&</sup>lt;sup>172</sup> Brief, *supra* note 14, at 9.

¶59 Admittedly, this is a difficult problem to overcome because people generally do not want to be forced into activity that they find uninteresting. Courts generally do not look favorably on compelling another person to work for someone if they do not wish to do so. There is no easy or sure solution to this problem. Contracting for this would be helpful, but not reliable. Of course, economic incentives are always a nice carrot. To entice a researcher to remain with a project, employment contracts might set out certain bonus levels, in addition to royalty payments, to be paid out if the inventor remains through certain phases of the project. Likewise, a private company investing in early-stage innovation could offer the same thing to a researcher. Also, employment agreements could contain provisions that would require an inventor to, in addition to the actual innovation, transfer all tacit and intimate knowledge along to the private company.

#### 3. Technology Transfer Offices

The use of contractual assignments by universities to protect their interest in the research that their faculty-inventors conduct appears to be an efficient approach to Bayh-Dole. However, the contract must take the proper form to remain efficient and superior to any problems that automatic vesting in the university has. A central concern with the contract scheme of Bayh-Dole is that the university may become the owner of many inventions and patent rights that they have no intention of pursuing or they lack the resources to commercialize. This outcome is contrary to the objectives of Bayh-Dole and needs to be remedied.<sup>173</sup> Through broad contracts, such as the one in Stanford, a university could be vested title to every invention that arises through the use of federal funds, whether they actually plan to pursue its commercialization or not. Furthermore, there is concern that even after the Stanford decision, universities are not amending their employment contracts to correct the deficiencies brought to light by Stanford.<sup>174</sup>

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While there are a fair number of universities that are categorically capable of commercializing their own inventions, there is a general inability to learn anything more from analyzing their technology transfer strategies. That is, rather unexpectedly, even the successful university-commercializers lack a general uniformity in technology transfer policy that one would expect. For example, two of the most successful research institutions, Johns Hopkins University and Massachusetts Institute of Technology ("MIT") have university-managed technology transfer offices.<sup>175</sup> Conversely, the University of Wisconsin, another incredibly successful research institution and a pioneer in university technology transfer, allows a private non-profit entity (the Wisconsin Alumni Research Foundation, or "WARF") to manage its patents.<sup>176</sup> Similarly uninformative, the technology transfer offices (TTOs) of these commercializing universities have, by all appearances on their websites, associates that represent a diverse field of expertise.<sup>177</sup> This is important because technology disclosures will (hopefully) emerge from a variety of fields, and possessing an expert in that particular area of research will help to ensure that the disclosure is properly understood to allow for more

<sup>&</sup>lt;sup>173</sup> 35 U.S.C. § 200 (2000) (acknowledging that the primary objective of Bayh-Dole is commercialization of federally-funded research discoveries).

<sup>&</sup>lt;sup>174</sup> Schacht, *supra* note 24.

<sup>&</sup>lt;sup>175</sup> Id. <sup>176</sup> Id. <sup>177</sup> Id.

efficient movement to commercialization.<sup>178</sup> However, the actual amount of associates staffed by these university TTOs does not help guide our understanding of what a successful university looks like. As stated above, there are experts at these TTOs with backgrounds in many different fields. However, MIT employs experts in nine unique fields,<sup>179</sup> while Johns Hopkins boasts 16 unique areas of expertise.<sup>180</sup>

On the other hand, there are some common outcomes shared by these "successful" universities. The top research universities all possess highly productive researchers. This quality seems intuitive, but it is worth noting that all researchers are not created equal. Furthermore, these more productive universities have a history of high industry participation and collaboration. However, it is unclear whether these traits led to the continued success, or whether the continued success led to these traits.

¶63 In sum, universities must honestly, and critically, self-evaluate their technology transfer capabilities. While similarities in certain aspects of TTO policies at these "successful" schools may occasionally arise, we still lack any consistency in policy implementation that we can point to and say "this is what makes commercialization at the university level work." For this reason, it is difficult for an outsider to analyze university policy and reach a conclusion regarding their potential to be successful commercializers. Therefore, individual universities, from within, must look at their own access to capital, staff adequacy and capabilities of their TTOs, and other intangibles that affect commercialization capabilities. If they do not possess the same resources as an MIT or Johns Hopkins (and they likely do not), then they have a responsibility to seek out alternative ways to get their invention out of their own hands and into the hands of those capable of doing so.

#### 4. Access to Venture Capital

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Congress sought to encourage the injection of risk capital into the development and commercialization of inventions in enacting Bayh-Dole.<sup>181</sup> As conceived under Bayh-Dole, universities and non-profits would retain title to any inventions that were created by their employees, thereby giving them the exclusive right to negotiate licensing with venture-backed companies willing to invest in those inventions.<sup>182</sup> This straightforward ownership model would encourage the venture capital investments necessary to commercialize these inventions because, for example, a start-up company (backed by venture capital) holding an exclusive license from a university would feel secure in the legitimacy of this license simply by pointing to the contract that they have with the university.<sup>183</sup> On the contrary, National Venture Capital Association (or "NVCA") members hesitate to invest substantial sums of money in a startup whose business plans are premised on licenses of technology of questionable ownership.<sup>184</sup> This problem manifests itself in two main ways when the inventor(s) is endowed with the ownership rights of their invention: (1) they may (perhaps unwittingly) enter into multiple,

<sup>&</sup>lt;sup>178</sup> Id.

 $<sup>\</sup>begin{array}{c} Id. \\ ^{181} Id. \text{ at } 2. \\ ^{182} Id. \text{ at } 1. \\ ^{183} Id. \text{ at } 6. \\ ^{184} Id. \text{ at } 7. \end{array}$ 

conflicting contracts (as seen in *Stanford*) regarding licensing of their invention, or (2) as is often the case, an invention may be the work-product of multiple inventors where ownership stakes are unclear. These two concerns are related, and the problem of multiple inventors has the potential to exacerbate the problem of revealing every contractual obligation related to an invention.

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NVCA members take substantial risk in investing in startups that seek to purchase licensing rights from universities and non-profits. According to The Economist, one "dollar's worth of academic invention or discovery requires upwards of \$10,000 of private capital to bring to market;" essentially, these venture capital-backed startups pay for over 99% of the innovation's final cost.<sup>185</sup> While such extraordinary claims cannot be easily substantiated, the costs of bringing such inventions to market can be significant. Venture capital firms already take on a tremendous amount of investment risk—that's the nature of the game, which is why it is so lucrative. However, if these firms must also fear that the licenses on which these investments are predicated may turn out to be unenforceable due to questions of ownership, they may be much more likely to conclude that the cost of the risk is not worth the investment.<sup>186</sup> This, of course, would result in the stifling of innovation and commercialization of necessary inventions that stand to positively impact the world. For the NVCA and its members, by vesting ownership rights in the university or non-profit receiving the federal funding, the Bayh-Dole Act creates a clear and predictable ownership framework. This framework allows the NVCA and its members to assess (and be compensated for) risk and invest in startups seeking to license these innovations and bring them to market.

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Venture capital-backed small businesses are changing the way that technologies are being created and commercialized in America's non-profits and universities under the Bayh-Dole Act. As expected, Venture Capital creates a double-edged sword: on the one hand, universities receive substantial funds from industry that are used to invest in additional research, thus creating the potential for greater breakthroughs that serve the public interest.<sup>187</sup> On the other hand, there is fear that venture capital is undermining the commercialization of patentable technologies by redefining the purposes of academic research, creating academic conflicts of interest and gambling on the more economically lucrative technologies while allowing the potentially more efficacious ones to spoil in their portfolios.<sup>188</sup>

#### B. Alternatives to University Commercialization

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There is ample empirical evidence to suggest that technology markets do not operate as efficiently as the university or the private sector desires.<sup>189</sup> Among organizations involved in "significant licensing activity," 47% of licensing negotiations,

<sup>&</sup>lt;sup>185</sup> Opinion, Innovation's Golden Goose, THE ECONOMIST (Dec. 12, 2002),

http://www.economist.com/node/1476653 [perma.cc/23AV-VSQZ]. <sup>186</sup> Brief, *supra* note 14, at 7.

<sup>&</sup>lt;sup>187</sup> Jeffrey A. Baumel, The Bayh-Dole Act: The Technology Revolution Shows Its Age, VENTURE CAP. REV. 17, 18 (Winter 2009).

<sup>&</sup>lt;sup>188</sup> Schacht, *supra* note 24.

<sup>&</sup>lt;sup>189</sup> Reiko Aoki & Aaron Schiff, Promoting Access to Intellectual Property: Patent Pools, Copyright Collectives and Clearinghouses, 38.2 R&D MGMT. 189, 193 (2008).

once commenced, ended unsuccessfully.<sup>190</sup> Failure was generally attributed to disagreement over financial terms, too many parties involved in the negotiation, or because a useful bundle of intellectual property could not be assembled.<sup>191</sup> At the university level, this problem can be exacerbated because of under-staffed and ill-equipped technology transfer offices. Problems also arise due to a general deficiency in legal knowledge by inventors and a lack of innovative knowledge by technology managers. With the goal of eliminating waste that results from squandered patents, universities must evaluate their own needs and capabilities. Some universities will be suited to follow an invention all the way from disclosure to commercialization. Many others, however, will need to assess alternative options that reward the university (in the form of royalties) for its initial investment, but subsequently take control of the intellectual property to satisfy Bayh-Dole's commitment to the commercialization of federally funded innovations.

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Three viable remedies exist for universities who underutilize their intellectual property: (1) intellectual property clearinghouse; (2) patent pools; and (3) patent auctions. The strengths and deficiencies of each access system will be discussed specifically; however, it is important to note that a particular system will not be appropriate for every research institution, type of intellectual property, or area of research. As stated earlier, adopting a policy to conform to Bayh-Dole cannot be a one-size-fits-all task. Each university will still be charged with recognizing the unique form that their discovery takes and the requirements that it entails, and determining which access system<sup>192</sup> is the most appropriate or most likely to result in the successful commercialization of that technology. For this reason, it will still be necessary for technology transfer offices (or at least technology transfer professionals) to remain on university staff to assist with this decision-making.

#### 1. Intellectual Property Clearinghouse

Bridging the gap between a patent holder and potential licensee is essential to efficient commercialization of intellectual property under Bayh-Dole. Throughout history, patent professionals (agents and lawyers) have played an indispensable role in matching inventors with parties who wish to develop and commercialize inventions.<sup>193</sup> In the late 1800s, purchasers of new technology would often consult with patent professionals about the merits of an invention before purchasing it.<sup>194</sup> These same patent professionals would also use nationwide networking connections to market patents to potential buyers in exchange for a fee. Acting as intermediaries, patent agents and lawyers helped improve the efficiency of patent trading by connecting buyers and sellers who normally would not have reached one another. Through their relationships with patent holders and prospective licensees, these agents were able to acquire specialized

<sup>&</sup>lt;sup>190</sup> Richard Razgaitis, *U.S./Canadian Licensing in 2005: Survey Results*, LES NOUVELLES (Dec. 2006), *available at* http://www.lesfoundation.org/pdf/2005SurveyResults.pdf [https://perma.cc/XBU4-WMCZ]. <sup>191</sup> *Id.* at 240.

<sup>&</sup>lt;sup>192</sup> Aoki & Schiff, *supra* note 189, at 195–97.

<sup>&</sup>lt;sup>193</sup> Kourtney Baltzer, Note, A Clearinghouse: The Solution to Clearing Up Confusion in Gene Patent Licensing, 24 HARV. J.L. & TECH. 519, 532 (2011).

<sup>&</sup>lt;sup>194</sup> Id.

knowledge regarding the wants and needs of the parties and match those interested expeditiously.<sup>195</sup>

- The idea of a technology clearinghouse was embraced by the federal government in ¶70 1986. As an amendment to the Stevenson-Wydler Act<sup>196</sup>, the Federal Technology Transfer Act codified alterations to the technology transfer process.<sup>197</sup> The Act also established the Federal Laboratory Consortium for Technology Transfer.<sup>198</sup> The consortium, among other things, functions as a clearinghouse, where an individual, company, or technology transfer office can search for available technologies by name or funding agency.<sup>199</sup>
- A third-party clearinghouse is an effective way to match providers and users of ¶71 information and innovations.<sup>200</sup> Optimally, federal contractors will be matched up with potential licensees (most commonly, from the private sector), either for the exchange of information concerning patented technologies or, ideally, for the arrangement of licensing agreements.<sup>201</sup> The clearinghouse acts as a middleman, facilitating exchanges between IP owners and IP consumers.<sup>202</sup> An intellectual property clearinghouse can take a variety of forms. Aoki & Schiff identify four unique classifications of clearinghouses: (1) third party informational; (2) third party licensing; (3) collective informational; and (4) collective licensing.<sup>203</sup> The designation of "third party" or "collective" refers to the ownership structure, while "informational" or "licensing" indicates the respective functions performed.
  - As we will see, the third party licensing clearinghouse is arguably the most effective structure for university-private industry technology transfer. However, to reach this conclusion we must briefly discuss the variations among each form. Ownership of the clearinghouse will affect the incentives and motivations by which it operates. The prices that a clearinghouse charges for its services, as well as the royalties that it sets will vary depending on whether it is owned and managed by a third party or as a collective.<sup>204</sup> Regardless of whether it is an independent non-profit or for-profit entity, or a voluntary association by a board of directors elected by the member organizations, the clearinghouse's status will dictate its goals, management styles, and mission. Relatedly, IP clearinghouses can either take the form of an informational clearinghouse or a royalty Informational clearinghouses only facilitate access to collection clearinghouse. information about intellectual property.<sup>205</sup> Services like Google's patent search<sup>206</sup> and

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<sup>&</sup>lt;sup>195</sup> *Id.* at 532–33.

<sup>&</sup>lt;sup>196</sup> Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701-14 (2006)).

<sup>&</sup>lt;sup>197</sup> Arnold Reisman & Aldona Cytraus, Institutionalized Technology Transfer in USA: A Historic Review (forthcoming) (Aug. 17, 2004), available at http://ssrn.com/abstract=585364 [https://perma.cc/E85D-8YZC]. <sup>198</sup> Id.

<sup>&</sup>lt;sup>199</sup> See Available Technologies Search Tool, FLC, http://www.federallabs.org/flc/available-technologies/ (last visited Aug. 13, 2013) [http://perma.cc/WC9D-MHVL].

<sup>&</sup>lt;sup>200</sup> Esther Van Zimmeren et al., A Clearinghouse for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Genetic Inventions?, 84 BULL. WORLD HEALTH ORG. 352, 353 (2006).

<sup>&</sup>lt;sup>201</sup> Baltzer, *supra* note 193.

<sup>&</sup>lt;sup>202</sup> Aoki & Schiff, *supra* note 189, at 195.

<sup>&</sup>lt;sup>203</sup> *Id.* at 196.

 $<sup>^{204}</sup>_{205}$  Id.

BirchBob<sup>207</sup> facilitate the informational exchange between IP owners and users, compiling databases for users to search for intellectual property. For example, Google's free service allows online searching of the full text of more than 7 million patents issued by the USPTO over the past 220 years.<sup>208</sup> Licensing clearinghouses, on the other hand, provide information, as well as issue standardized licenses and collect and distribute royalties.<sup>209</sup>

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The clearinghouse structure most conducive to efficient and expedient technology transfer leading to commercialization between universities and private industry must take the form of a third party licensing operation. It is unlikely that any collectively run clearinghouse would succeed for many of the same reasons that Bayh-Dole has fallen short. The diverse interests of the universities, inventors, and private industry highlight the potential problems in an IP collective clearinghouse. The operation would turn inefficient relatively quickly, in the same manner that negotiations on the free market between universities and private industries often do. For this reason, a clearinghouse that effectively facilitates IP transactions between a university and a business must be a neutral third party. Furthermore, the most effective clearinghouse would not only possess informational databases, searchable by organization members, but also have the power to license the intellectual property and collect and disperse royalties.

An intellectual property clearinghouse that is owned and operated by a third party and has power to license and collect royalties is optimal for universities to move information quickly from their laboratories into the hands of companies with the ability to commercialize. Not only does this structure have the ability to centralize information, but it has independence and is free from biases in licensing transactions, improving economic efficiency.<sup>210</sup>

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The unique advantages that a third party licensing clearinghouse provides have the ability to satisfy the wide array of interests that have historically bogged down the application of Bayh-Dole. The problems discussed earlier that have plagued Bayh-Dole and were brought to light in *Stanford* will be greatly alleviated when universities elect to join a clearinghouse that connects their role as researchers and innovators with the private industry's desire to commercialize and market new inventions.

Both information and licensing clearinghouses have the ability to provide an online, searchable database, which is a necessary condition for effective technology transfer between university and industry.<sup>211</sup> The centralization of information about patents facilitates more effective dissemination of knowledge than individual investigations performed by small-scale licensees.<sup>212</sup> A searchable database satisfies both university and industry interests, as well. This format allows for a private company to conduct a search for available intellectual property using little more than relevant search terms, eliminating the need for investigators and agents to contact university technology transfer offices individually. Conversely, universities benefit from the ability of member

<sup>&</sup>lt;sup>206</sup> See GOOGLE PATENT SEARCH, http://www.google.com/patents (last visited Feb. 10, 2016) [http://perma.cc/5MKE-XSEC].

See BIRHBOB, http://www.birchbob.com (last visited Feb. 10, 2016) [https://perma.cc/M9B3-KC3Z]. <sup>208</sup> Aoki & Schiff, *supra* note 189, at 196.

<sup>&</sup>lt;sup>209</sup> Id.

<sup>&</sup>lt;sup>210</sup> Baltzer, *supra* note 193, at 533.

<sup>&</sup>lt;sup>211</sup> *Id.* <sup>212</sup> *Id.* 

businesses to upload their technology needs to a searchable database designed for the university to look for potential licensees. This most basic feature of a clearinghouse is a crucial first step to bridging the gap between business and university.

The most beneficial functions of a licensing clearinghouse are overseeing and streamlining licensing deals.<sup>213</sup> A central problem that technology transfer faces under Bayh-Dole is the university's rigid, almost unreasonable stance on licensing negotiations.<sup>214</sup> University blanket approaches to negotiations, such as never granting indemnity and never making representations regarding originality, are harmful to intellectual property transfer and commercialization.<sup>215</sup> Such unwavering positions prevent fruitful negotiations between the university and industry: often universities are in the best position to control the risk, yet want to transfer the risk to the company, often without compensation for this additional exposure.<sup>216</sup> A third party licensing clearinghouse can alleviate this problem through its ability to standardize licensing negotiations and contracts, set licensing prices, and oversee licensing deals.<sup>217</sup> Standardized licenses containing essential and immutable clauses reduce the transaction costs associated with the time and energy spent on negotiation. Lynda Covella and David Newman suggest that the essential clauses contained in every deal include, inter alia, licensed subject matter, field of use, license rate, and term of the license.<sup>218</sup> All other non-essential clauses would be standardized as much as possible.<sup>219</sup>

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Standardizing all of the clauses that are commonly negotiated over will require concessions by both parties, but will greatly reduce legal expenses associated with these often lengthy and frustrating discussions. Furthermore, it will minimize instances of a party walking away from a transaction because of disagreeable conditions: both the university and the company will be aware of what their obligations are. Relatedly, the clearinghouse would streamline the license pricing methodology. Patent examiners, attorneys, and agents employed by the clearinghouse, in partnership with financial professionals, would resolve uncertainty regarding intellectual property value.<sup>220</sup> In a field not easily anchored by a particular valuation measure, universities and companies benefit from pricing set by independent experts that both parties can rely on now and use as estimates when valuing intellectual property in the future. This eliminates the typical use of licensee opening bids to set the value of an invention.<sup>221</sup>

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Furthermore, a licensing clearinghouse can organize and oversee licensing deals in a way that informational clearinghouses cannot. With the information and knowledge collected about numerous patent holders, the clearinghouse could bundle a variety of licenses from a number of universities to license to a company as a package. This

<sup>&</sup>lt;sup>213</sup> *Id.* at 534.

<sup>&</sup>lt;sup>214</sup> John E. Tyler III, Advancing University Innovation: More Must Be Expected—More Must Be Done, 10 MINN. J.L. SCI. & TECH. 143, 189–201 (2009).

<sup>&</sup>lt;sup>215</sup> *Id.* at 189.

<sup>&</sup>lt;sup>216</sup> *Id*.

<sup>&</sup>lt;sup>217</sup> Baltzer, *supra* note 193, at 534–35.

<sup>&</sup>lt;sup>218</sup> Lynda Covella & David Newman, Standardizing Patent License Agreements: A Method of

Evaluating What May Be Standardized, 2010 LICENSING EXECUTIVES SOC'Y 2,

http://www.gtlaw.com/NewsEvents/Publications/PublishedArticles?find=146924 [https://perma.cc/3BKE-Q3VS]. <sup>219</sup> *Id*.

<sup>&</sup>lt;sup>220</sup> Baltzer, *supra* note 193, at 535.

<sup>&</sup>lt;sup>221</sup> *Id*.

advantage eliminates the need for a licensee to contact each individual patent holder to negotiate a license.<sup>222</sup> Essentially, the clearinghouse serves as a one-stop-shop for a potential licensee to find the combination of patents that it needs for its particular technology. The university also benefits from this feature where it may possess an invention that is unmarketable on its own, but able to be licensed and earn royalties when bundled with complementary technology from other universities.

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Finally, the third party licensing clearinghouse can enforce the licensing contracts, monitor for infringement, and compel alternative dispute resolution between aggrieved parties. The cost for a clearinghouse to monitor the use of licenses to detect any patent infringement is likely considerably less than the cost for each university to monitor each of their licenses. The cost of this service would, naturally, be deducted from the royalty payments dispersed to a university. The clearinghouse, as one of its essential functions, would have a duty to perform these investigatory functions to detect patent infringements. Having access to information regarding all of their member licensees makes this task simpler. Furthermore, the clearinghouse can periodically contact licensors to inquire as to whether they have been made aware of any possible IP infringements and employ a staff of professionals who monitor media outlets for potential infringements.<sup>223</sup> In addition, the clearinghouse can compel arbitration or mediation in disputes arising between the university and private industry.<sup>224</sup> Patent litigation costs are exorbitant.<sup>225</sup> and thus both patent holders and licensees will find this option more appealing. Compulsory arbitration or mediation could be included in one of the essential clauses found in every licensing agreement, discussed above.<sup>226</sup>

In today's world, university-industry collaboration is seldom disrupted by spatial or geographical limitations. An eager buyer can seamlessly connect with a willing seller anywhere on Earth. However, intellectual property transactions remain subject to disparate knowledge between parties, which creates an information gap and reduces efficiency to the same or to a higher degree than any physical distance would.<sup>227</sup> Furthermore, inflexible and unreasonable negotiation strategies are counter-productive to achieving mutually beneficial licensing agreements. An intellectual property clearinghouse tailored to fit the unique interests of both the universities and the private industry can alleviate these concerns and efficiently facilitate technology transfer pursuant to the goals of Bayh-Dole.<sup>228</sup> Uniform licensing agreements, third party patrolling and enforcement of intellectual property transfer, and open access to the innovations possessed by universities and the technologies needed by industry are central to more efficient commercialization of socially beneficial inventions born from federal funding.

<sup>228</sup> 35 U.S.C. § 200 (2000).

<sup>&</sup>lt;sup>222</sup> *Id.* at 534.

<sup>&</sup>lt;sup>223</sup> Baltzer, *supra* note 193, at 536–37.

<sup>&</sup>lt;sup>224</sup> Id.

 $<sup>^{225}</sup>$  *Id*.

<sup>&</sup>lt;sup>226</sup> Id.

<sup>&</sup>lt;sup>227</sup> See Naomi R. Lamoreaux & Kenneth L. Sokoloff, *Intermediaries in the U.S. Market for Technology* (Nat'l Bureau of Econ. Research, Working Paper No. 9017, 2002), http://www.nber.org/papers/w9017 [https://perma.cc/HE6N-HTG9].

2. Patent Pools

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An alternative proposal to an intellectual property clearinghouse is that universities search for, identify, and join patent pools of complimentary patents. The responsibility to identify complimentary technologies and create or join a pool would fall on a university's technology transfer office. Once the TTO receives the intellectual property assignment, they would be charged with searching for existing pools containing technologies that would complement their own, or joining a network whereby new pools can be created through the coming together of technologies possessed by multiple institutions. Because we are contemplating alternatives for universities unable to commercialize innovations themselves, we will only discuss patent pool licensing to third parties. However, it should be noted that that the cross-licensing of patent pool patents amongst the members of a single pool also occurs.

In most areas of research, individual discoveries have resulted in the issuance of **¶83** many patents, "each constituting an essential element of a larger information base."<sup>229</sup> As a result, for any firm to make use of these new technologies, more and more often they have to acquire multiple intellectual property rights.<sup>230</sup> This becomes a severe hindrance to commercialization when the patents are not owned by the same entity. Rudy Santore et al. point to the elements of a human gene as an example of the entanglements that arise from multiple patent owners.<sup>231</sup> Several institutions may hold the intellectual property rights to separate regions of genes, markers of specific gene attributes and functions, and tools of research.<sup>232</sup> The development of any beneficial technology will likely require the developer to negotiate licenses with each individual holder of each element. As should be clear, this is an inefficient way to promote commercialization. The issue becomes increasingly frustrated when the university owner does not possess the resources to cross-license complimentary technologies to promote commercialization, but still holds out on negotiating their individual patent. When complementary patents are licensed jointly as a package, obtaining a single license from the patent pool means that the licensee has access to all of the intellectual property covered by the patents in the pool.<sup>233</sup>

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Administration of the patent pool can take a variety of forms; however, not all forms are appropriate for universities. A third party management organization can administer a patent pool on behalf of the pool members, or one of the members of the pool can take on the responsibility and manage on behalf of all of the members.<sup>234</sup> When forming or joining a patent pool, a university TTO must insist that management is a third party non-member. A university unable to successfully license its own intellectual property by itself should not be in charge of licensing a pool of IP. Similar to a clearinghouse, a third party administrator has an incentive to quickly and efficiently license the patent pool to those readily able to commercialize.

<sup>232</sup> Id.

<sup>234</sup> *Id.* at 195.

<sup>&</sup>lt;sup>229</sup> Rudy Santore, Michael McKee, & David Bjornstad, Patent Pools as a Solution to Efficient Licensing of Complementary Patents? Some Experimental Evidence, 53 J. LAW & ECON. 167, 167 (2010).

 $<sup>^{230}</sup>$  *Id*.

 $<sup>^{231}</sup>$  *Id.* at n.1.

<sup>&</sup>lt;sup>233</sup> Aoki & Schiff, *supra* note 189, at 194–95.

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#### 3. Patent Auctions

¶85 A relatively new forum for technology and patent monetization, live patent auctions, were begun in April, 2006 by a Chicago IP consulting firm, Ocean Tomo.<sup>235</sup> Although a truly innovative and "first-of-its-kind event",<sup>236</sup> the live patent auction has generally failed to take off as was expected. Ocean Tomo's first auction offered sixtyeight lots, yet only sold 26 (roughly 38%).<sup>237</sup> In 2007, the first European intellectual property auction was held in Germany. Despite these numbers, Ocean Tomo's auctions have shown some potential.<sup>238</sup>

Patent auctions have the potential to be an efficient medium for universities to ¶86 move patents into the hands of private companies eager to commercialize them. Auction houses match sellers and buyers of intellectual property without the university expending its own limited resources to do so. Furthermore, auctions reduce transaction costs by eliminating lengthy and arduous negotiations in favor of a fast-moving auction block.<sup>239</sup> This also cures inefficiencies resulting from unreasonable negotiation and licensing terms favored by universities regarding certain representations and warranties. Auctions would issue standard, uniform contracts when facilitating the sale of patents from holder to purchaser.

On the other hand, there is concern that patent auctions, even if they were viable options for universities as a way to get patents into the hands of those able to commercialize them, create an environment ripe for so-called patent trolls.<sup>240</sup> These patent trolls have no plans to commercialize the patent, but rather make their money from threats of litigation against alleged patent infringers.<sup>241</sup> Fawcett and Chan fear that patent auctions eliminate some of the hurdles that patent trolls faced when attempting face-toface negotiations with a patent holder.<sup>242</sup> At a live auction, the auction house closely guards the anonymity of both bidders and sellers. While this move facilitates inability for competing companies to get a leg-up on what markets competitors may be entering or exiting, it also allows for patent trolls to anonymously purchase patents where they would otherwise be blocked from doing so. A research institution would likely be very wary about entering into face-to-face negotiations with a known patent troll, if for no other reason than this is antithetical to Bayh-Dole. However, where a seller does not know the identity of their purchaser, these safeguards against non-commercialization cannot be protected.

<sup>&</sup>lt;sup>235</sup> Michelle Tyde & Andrea Bates, *The New IP Marketplace: Patent Auctions*, GT ALERT (Apr. 2006); John Jarosz et al., Patent Auctions: How Far Have We Come?, LES NOUVELLES 11 (Mar. 2010), http://www.analysisgroup.com/uploadedfiles/content/insights/publishing/jarosz patent auctions how far have we\_come.pdf [https://perma.cc/LR7Z-2KU3].

Tyde & Bates, *supra* note 235.

 $<sup>^{237}</sup>$  *Id*.

<sup>&</sup>lt;sup>238</sup> Adam Andrzejewski, Patent Auctions: The New Intellectual-Property Marketplace, 48 U. LOUISVILLE L. REV. 831, 836-37 (2010).

<sup>&</sup>lt;sup>239</sup> *Id.* at 837.

<sup>&</sup>lt;sup>240</sup> Matthew Fawcett & Jeremiah Chan, *March of the Trolls: Footsteps Getting Louder*, 13 INTELL. PROP. L. BULL. 1, 11 (2008).

<sup>&</sup>lt;sup>241</sup> Tyde & Bates, *supra* note 235. <sup>242</sup> Fawcett & Chan, *supra* note 240.

- Furthermore, the patent auctions that exist now sell patents both in individual lots **88** and bundles.<sup>243</sup> This is an efficient and expedient way to bundle complementary patents from a single patent holder and move them to a purchaser; for example, each lot that Ocean Tomo puts up for auction contains on average three patents.<sup>244</sup> However. universities often need to only sell one patent at a time, or multiple patents that often are not complementary and arise out of different research focuses. Since auctions are able to sufficiently accommodate the selling of individual patents rather than lots, they will likely be suitable for universities as a means to quickly move patents to the private sector.
- Currently, patent auctions are still in their infancy and are used as a mechanism for ¶89 bankrupt companies to liquidate some of their assets.<sup>245</sup> However, once a more developed infrastructure is created to facilitate the sale of individual patents quickly and in a manner that can prevent the infiltration of patent trolls, the patent auction has the potential to be used on a university scale.

#### CONCLUSION

¶90 Since its enactment, Bayh-Dole has made significant improvements to the process by which federally funded research is commercially developed and the benefits brought to the consuming public. The universities that lie at the heart of this process play a critical role in managing the implementation of the Act's goals and objectives. If managed properly, this technology transfer can prove to be financially rewarding to the university and the economy. If managed poorly, valuable research can find its way into the black hole of the technology transfer office, never to find a commercial application. Because the university invention disclosure process may require that the researcher refrain from publishing the results of their research prior to exploring the possibility of patent opportunities, this black hole can also impair the inventor's scholarship prospects.

Universities must perform a self-assessment to determine what technology transfer strategy should be adopted for their particular institution. Such a strategy must be developed in collaboration with faculty inventors and the private sector, taking into consideration the competing interests of the participants and the economic realities of the local and regional ecosystem. In the event that a particular university's research base and economic realities do not warrant internal expenditures to fully implement such a strategy and requisite management function to achieve Bayh-Dole's objectives, they are left with two choices: They can disclose the invention to the funding agency and not take ownership, or disclose and pursue an outside mechanism such as an intellectual property clearinghouse, patent pool or auction to further promote commercialization.

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<sup>&</sup>lt;sup>243</sup> John Jarosz et al., Patent Auctions: How Far Have We Come?, 45 LES NOUVELLES 11, 17 (2010). From the spring of 2006 to the summer of 2009, 170 individual patent lots were sold and 97 lot bundles were sold. During that time, 641 patents were sold, comprising 282 lots. Id.

<sup>&</sup>lt;sup>244</sup> See id. at fig.2.
<sup>245</sup> Andrzejewski, *supra* note 238, at 835.