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# The Bayh-Dole Act, Creating Products or Profits?

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Independent Study  
Professor Rooksby

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## Introduction

Since the inception of the patent system, tax dollars were used to pay inventors to develop and patent their Federal Funded (FF) inventions.<sup>1</sup> Many public benefits are paid for by taxes such as police, military, infrastructure, schools and much more.<sup>2</sup> However, FF inventions are not necessarily free for the public to use. This has led to a discussion of why the public may be “paying twice” for FF inventions.

FF inventions contribute large amounts of revenue to the economy. Technology licensing from FF inventions between 1996 and 2007 contributed as much as \$187 billion to the US gross domestic product and \$457 billion to gross industry output.<sup>3</sup> FF inventions should be closely watched, as allowing profits in excess of the incentive required for commercialization of an invention may produce a loss to society.<sup>4</sup>

Revenue from patent rights has been an incentive to develop FF inventions in commercial products. The “Revenue from university-owned patents often goes toward funding more research, reducing the need for government funding and thereby funding research by taxing those using the technology, rather than the population in general.”<sup>5</sup> Patents on FF inventions are

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<sup>1</sup> Peter Lee, *Patents and the University*, 63 DUKE L. J. 1 (2013).

<sup>2</sup> Yair Listokin & David M. Schizer, *I Like to Pay Taxes: Taxpayer Support for Government Spending and the Efficiency of the Tax System*, 66 TAX L. REV. 179 (2013).

<sup>3</sup> Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, 2(52) SCI TRANSL MED, Oct. 6 2010, at 52cm27.

<sup>4</sup> See Sean Flynn ET AL., *An Economic Justification For Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED & ETHICS 184, 186 (2009) (“The second loss from monopoly pricing is “deadweight loss” from forgone transactions, which would have taken place at the lower competitive price. These lost sales are known as “deadweight” because they do not create surplus for the buyer or seller... In pharmaceutical markets, the deadweight loss is often referred to as the problem of “access”: the poor cannot purchase a drug product because of its high price, and as a result, are untreated”).

<sup>5</sup> Gary Pusinelli, *Share and Share Alike: Increasing Access to Government Funding Inventions Under the Bayh-Dole Act*, 7 MINN. J.L. SCI. & TECH. 393, 413 (2006).

used to promote research and to provide an incentive to invest in the technology. This way, each FF dollar will actually fund more research than its face value.

The Bayh-Dole Act (BDA) increased the ease that an inventor could obtain patent rights in an FF invention in the hopes of creating more products from the inventions. It created an emphasis on patenting and licensing FF inventions to industry.<sup>6</sup> The BDA has created a structure for determining the rights of inventors involved in the FF invention and has facilitated the evolution of FF inventions from conception in universities to application in industry. The exact impact of the BDA has been disputed whether or not it is benefiting the public.

Universities' rights in FF inventions were changed when the BDA was passed due to their large receipt of federal funds.<sup>7</sup> Universities, as public created entities, are geared towards education and promoting the public interest. Following these goals, universities were initially reluctant to enforce their patents against public use since they have paid for the invention. However, universities still spend money to develop FF inventions and must recover their costs. They have been able to recover these costs through patent enforcement. This has led to “[M]ounting economic pressures cast[ing] doubt on any optimism for a decrease in university participation as plaintiffs in patent infringement litigation in years to come.”<sup>8</sup> Universities are asking the public to pay for the use of their FF inventions.

Some abuse FF inventions for their own profits, while others try to only recover costs they have spent in order to turn the invention into a commercial product and promote further

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<sup>6</sup> DAVID C. MOWERY ET. AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* 7 (2004).

<sup>7</sup> Robert E. Litan & Lesa Mitchell, *A Faster Path from Lab to Market*, HARVARD BUS. REV., Jan. 2010, 52 (2010).

<sup>8</sup> Jacob H. Rooksby, *Innovation and Litigation: Tensions Between Universities and Patents and How to Fix Them*, 15 YALE J.L. & TECH. 312, 356 (2013).

research. It is a far-reaching goal to create a perfect system where FF inventions generate the exact amount of revenue to recover costs involved during development. Most of the time companies do not develop products to only get their money back. Profits are needed to create an incentive for further development. The “patent system must be related to the world of commerce rather than to the realm of philosophy.”<sup>9</sup> The goal of the system therefore must be to restrict excessive profits, not eliminate them entirely.

This article will analyze the BDA’s impact and ways to improve it. The article will start out by analyzing the background of the patent system and how patents are enforced in Part I. It will discuss the balance of providing a monopoly in order to promote advances in technology. Then in Part II the article will analyze the current state of Intellectual Property rights in universities, how they use those rights to generate revenues and the impact the BDA has on universities. Further, it will look into how universities may be abusing FF inventions for their own profits, a goal which was not proposed by the BDA.

Many commentators have solutions to restrict excessive profits from FF inventions; however they lack practical application and contain philosophical arguments not grounded in reality. In Part III, the article will discuss the approaches proposed by others for curbing excess profits. It will discuss the positives and negatives of these approaches. The article will also propose a few alternative solutions to curb excess profits and improve the effectiveness of the BDA.

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<sup>9</sup> Brenner v. Manson, 383 U.S. 519, 536 (1996) (*citations omitted*).

## Part I: The Purpose of Patent

A patent is an “exclusive right to an invention as given not of natural right, but for the benefit of society.”<sup>10</sup> Patents are granted for “the public good [which is] . . . the motivating principle behind the award of any patent.”<sup>11</sup> The patent statute rewards the “inventor” not the “pure scientist.”<sup>12</sup> A patent is to provide “encouragement to [inventors] to pursue ideas which may produce utility.”<sup>13</sup> Patent law has operated on this premise since 1790.<sup>14</sup> Patents are granted to inventors in order for society to benefit from the invention.

A patent is a right to exclude that is derived from Congress’s constitutional power to promote the useful arts.<sup>15</sup> The United States Constitution says “[t]he Congress shall have Power to . . . promote the useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective Writings and Discoveries . . .”<sup>16</sup> Congress took this authorization and granted patentees the right to exclude others.<sup>17</sup> This right has manifested itself in the patentee’s right to sue infringers. The patentee has the right to sue for infringement against anyone who “makes, uses, offers to sell, or sells any patented invention within the United States or imports

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<sup>10</sup> Thomas Jefferson, *Thomas Jefferson to Isaac Mcpherson*, in WRITINGS OF THOMAS JEFFERSON, (Andrew A. Lipscomb and Albert Ellery Bergh, Washington Thomas Jefferson Memorial Association, 20 vols., 1905).

<sup>11</sup> Jacob H. Rooksby, *Myriad Choices: University Patents Under the Sun*, 42(2) J. L. & ED. 313, 313 (2013) (hereinafter *Rooksby II*).

<sup>12</sup> *Vitamin Technologists, Inc. v. Wis. Alumni Research Found.*, 58 U.S.P.Q. (BNA) 293, 295 (9<sup>th</sup> Cir. 1943).

<sup>13</sup> Jefferson, *supra* note 10. *See also* *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996) (Where they discuss patent rights are granted to the person who the invention belongs).

<sup>14</sup> *Brd of Trs of the Leland Stanford Junior Univ. v. Roche Molecular Systems*, 563 U.S. \_\_\_\_ Inc. 131 S.Ct. 2188 (2011) (citations omitted).

<sup>15</sup> F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 697 (2001).

<sup>16</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>17</sup> Pusinelli, *supra* note 5, at 413.

into the United States any patented invention during the term of the patent.”<sup>18</sup> Congress has used its constitutional power to promote the useful arts by giving patentees an “authorization to sue for infringement.”<sup>19</sup>

“[T]he existence of the patent system’s impact is beyond dispute.”<sup>20</sup> However, the exact extent of the impact is debated.<sup>21</sup> The impact can be measured from monetary gains generated by patents, jobs created, or even the progress of science as a whole. Any one of these methods is difficult to quantify and it may not encompass the entire impact of the system. Intense investigation is required to determine if the patent system is used to “promote the useful Arts.”<sup>22</sup> Determining whether the benefit the patent system has on society is positive or negative is a difficult task to undertake.

Measuring the effect patents have on technology may be difficult due to the advancement of the technological field. “Patented inventions face the competitive pressure of time.”<sup>23</sup> New patented products, during infancy of the patent term, have competition from the products they have replaced.<sup>24</sup> New patented products are expensive, due to the monopolistic control given by a patent right. In contrast, older products are typically cheaper, since they have had the opportunity to find the best manufacturing processes and will want to stay competitive with the newer product. Later in the term of a patent, it faces the opposite competition, the newer product, which it once was.<sup>25</sup> The quicker an invention becomes obsolete to newer inventions it may

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<sup>18</sup> 35 U.S.C. § 271(a) (2010).

<sup>19</sup> Rooksby, *supra* note 8, at 358

<sup>20</sup> Kieff, *supra* note 15, at 698.

<sup>21</sup> *Id.* at 698.

<sup>22</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>23</sup> Kieff, *supra* note 15, at 730.

<sup>24</sup> Edmund W. Kitch, *Patents: Monopolies or Property Rights?*, 8 RES. L. & ECON. 31, 31 (1986).

<sup>25</sup> Kieff, *supra* note 15, at 730.

effectively end the patent term early for that invention, since there is no longer a demand for the invention. The speed at which a technological field develops can affect the incentive required to encourage new products.

Each technical field requires a varying amount of research and development (R&D) costs. The R&D of a new pharmaceutical in the United States averages 10 to 15 years and costs \$800 million dollars.<sup>26</sup> In contrast, developing a new coffee mug would require substantially less R&D. Additionally, the pharmaceutical industry is particularly susceptible to “rip-off” pharmaceuticals due to the fact that chemicals are easily replicable.<sup>27</sup> In order for a company to want to pursue development of the product there needs to be an incentive, e.g. profits.

The costs from R&D have to be recovered in future sales of the product. University patenting and licensing has become particularly concentrated in the biotechnology field due to the high start-up costs.<sup>28</sup> Other technological fields may require substantially less money and time to develop new products than in the biotechnology field. This means the incentive needed for a company to engage in the development of a new product is substantially less.<sup>29</sup> The variable amount of incentive required for each technological field increases the difficulty in determining the patent system’s effect.

### **A. Patent Licensing and Enforcement**

The patent system, overall, has undoubtedly affected the economy. The patent system has had an impact on long-term international competitiveness as it promotes national economic

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<sup>26</sup> Taiwo A. Oriola, *Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy*, 2007 U. ILL. J.L. TECH. & POL’Y 287, 311 (2007).

<sup>27</sup> Oriola, *supra* note 26, at 312.

<sup>28</sup> Mowery, *supra* note 6, at 2.

<sup>29</sup> A Samuel Oddi, *Plagues, Pandemics, and Patents: Legality and Morality*, 53 IDEA 1, 14 (2011).

growth.<sup>30</sup> Patents give the owner the ability to negotiate licenses with those wanting to make, use, offer to sell, sale or import their inventions. These licenses can be non-exclusive (licensed to anyone willing to pay) partially exclusive or exclusive (restricted licensing).<sup>31</sup>

A patent holder uses an exclusive license to restrict those who may license their patent, usually to provide a benefit to the exclusive licensee. “Exclusive licenses can generate windfall profits to licensees. . .[,] but at the cost of diminished dissemination and possible reduction in follow-on R&D that comes when only one company is permitted to exploit a patent.”<sup>32</sup> “[R]estrictive licensing policies can limit the diffusion and use of an invention or related knowledge.”<sup>33</sup> However, for the pharmaceutical industry, this may be the only way for the patentee to recover costs in developing their inventions. If many could obtain a license they could effectively ride on the first licensee’s coat tails in proving out the methods of development and FDA trials. No one would want to be the first licensee. Without the exclusive license as an incentive for development, it is possible that the patented invention may never be developed into a product.

Universities, as patentees, can agree to license their patents in varying ways. This decision is usually dependent on the costs the university incurred in development and the likelihood they will recover their costs in the license. There are usually costs still to be incurred for further development leading to a product. Another consideration is the ease someone could duplicate the invention once it is in the public domain.<sup>34</sup> However,

[T]he potential to generate revenue through licensing patents can create incentives for universities to license their patents exclusively, which can lead to what

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<sup>30</sup> Kieff, *supra* note 15, at 698.

<sup>31</sup> 35 U.S.C. § 208 (1984).

<sup>32</sup> Rooksby II, *supra* note 11, at 318.

<sup>33</sup> Mowery, *supra* note 6, at 2.

<sup>34</sup> Rooksby II, *supra* note 11, at 315-6.

amounts to monopolistic control by companies of new drugs, diagnostic tools, or other products of great importance to the public's health and welfare.<sup>35</sup>

There are no restrictions on the procedures or methods a university may use to extract benefits from their patent rights. They may end up extracting profits in excess of their costs.

The debate from many commentators has been whether universities should be able to license FF inventions and use them to generate profits. Determining the correct amount to recover under a license is difficult for a university to determine when, in the early stages of development, the commercial worth and costs require in commercializing the invention into a product are uncertain.<sup>36</sup> Many universities may be “[B]etter to license a patent of uncertain market potential.”<sup>37</sup> Licensing is where the universities most appropriately utilize their patent rights.

Some patents can be considered blocking a field of technology, e.g. a blocking patent. That is to say the patent prevents further advances in the field unless you are able to license it. This may create prohibitive costs to research in a particular field. One historic way of clearing the blocking patents was to create a patent pool. “Patent pools solve specific problems, such as the clearing of blocking patents or protecting against ‘hold up’ or ‘hold out’ by individual patent holders.”<sup>38</sup> Patent pools may be useful to promote commercialization of FF inventions.

“Patent pools are collective licensing arrangements in which two or more parties grant licenses to their respective intellectual property to each other or to a third party that sub-licenses the pooled technology to others.”<sup>39</sup> Historical patent pools, however, ultimately required

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<sup>35</sup> *Id.* at 315-6.

<sup>36</sup> Rooksby, *supra* note 8, at 328.

<sup>37</sup> *Id.* at 328.

<sup>38</sup> Scott Sher ET AL., *The Role of Antitrust in Evaluating the Competitive Impact of Patent Pooling Arrangements*, 13 SEDONA CONF. J. 111 (2012).

<sup>39</sup> Sher, *supra* note 38.

government intervention to get the pool started.<sup>40</sup> Further, patent pools are only allowed when they permit the participants to generate substantial efficiencies they could not otherwise obtain.<sup>41</sup> Patent pools are formed out of necessity not as a predetermined means of ensuring innovation.

Patent pools may raise the costs of developing competing technology.<sup>42</sup> As a collection of patents, a patent pool can be a monopoly of the technology in a particular subject field, in other words, a monopoly of monopolies. Professors Ryan Lampe and Petra Moser performed a study that found patent pools actually had the effect of discouraging innovation.<sup>43</sup> Patent pools usually require the person wanting to join a patent pool to license all relevant Intellectual Property (IP) to the patent pool.<sup>44</sup> Patent pools can lead to higher start-up costs, uncertainty on returns, and monopolistic control of invention fields.

### **B. Patent Enforcement by Non-Practicing Entities**

Litigation by a Non-Practicing Entities (NPEs) has become a concern over the past decade.<sup>45</sup> NPEs do not create the commercial product themselves.<sup>46</sup> They will attempt to license their patents or use them to sue a potential infringer instead of undertaking the commercialization themselves.<sup>47</sup> Universities, which may operate as NPEs, “are not in the business of commercializing their patents through direct manufacturing, distribution, and marketing of any

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<sup>40</sup> Pusinelli, *supra* note 5, at 429-30.

<sup>41</sup> Sher, *supra* note 38.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 114 (citing Ryan Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from 20 industries in the 1930s*, (Dec. 2, 2011) (unpublished manuscript) (on file with authors).

<sup>44</sup> Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1414 (2007).

<sup>45</sup> Thomas H. Kramer, *Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals*, 39 DEL. J. CORP. L. 467, 469 (2014).

<sup>46</sup> Kramer, *supra* note 45, at 467.

<sup>47</sup> eBay Inc. v. MerExchange, L.L.C., 547 U.S. 388 (2006).

ultimate products or services their patents cover.”<sup>48</sup> They have to partner (license IP) with industry to get products to market. Universities must be able to license their IP in order to recover costs incurred during development of that IP.

The monopolistic prices created from patent rights in FF inventions have been a cause of public debate. For example, Carnegie Mellon University recently won a settlement of \$1.17 billion in a patent infringement suit.<sup>49</sup> Further, a university patent handler, Wisconsin Alumni Research Foundation (WARF), which manages the University of Wisconsin’s patents, has been particularly controversial. They have received criticism for threatening patent enforcement.<sup>50</sup> It seems unlikely that a billion dollar plus verdict on a FF invention is in the “public interest.”

Assertion of patent rights is a large burden to society. “[T]he direct cost of NPE assertions is \$29 billion annually, and lobbying by affected industries.”<sup>51</sup> Patent Assertion Entities (PAEs) are a particular type of NPE that have an interest in patents only to extract payment in the form of licenses or royalties from another. Patent trolls are the most heinous PAEs whose extraction of profits from patents amounts to a level similar to extortion. They are only interested in extracting revenue from patents with total disregard for the state of technology or advancement of the field. Patent trolls are like pirates, “an enemy to all mankind.”<sup>52</sup>

A patentee has a choice of how to enforce their patent rights through money damages or an injunction. A preference for not making products and instead extracting profits from others is

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<sup>48</sup> Rooksby, *supra* note 8, at 327-8.

<sup>49</sup> Rich Lord, *Carnegie Mellon Wins \$1.17 Billion in Patent Case*, PITTSBURGH POST-GAZETTE, Dec. 27, 2012, at B1.

<sup>50</sup> Henry Etzkowitz, *Knowledge as Property: The Massachusetts Institute of Technology and the Debate over Academic Patent Policy*, 32 MINERVA 383, 386(1994); *See also* Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303, 103 U.S.P.Q.2d 1681 (Fed. Cir. 2012).

<sup>51</sup> Kramer, *supra* note 45, at 467.

<sup>52</sup> *United States v. Smith*, 18 U.S. 153, 5 L. Ed. 57 (1820).

not against the law as was discussed in *eBay v. MerExchange*.<sup>53</sup> Those who “do not produce any products . . . may still be eligible to receive injunctions against parties infringing their patents.”<sup>54</sup> A patentee’s remedy in an infringement lawsuit is not based on their status as a PAE, NPE or manufacturer.

An injunction is grounded in equity and in the case of patents is usually an order to stop producing the infringing product or practicing the infringing method or use.<sup>55</sup> Injunctions can be devastating to an infringer. They could have invested capital in order to practice the invention and are now forced to stop practicing it. In other words, they are not going to recover the invested capital. Further, by stopping practice of the invention it becomes less available to the public.

In *Ebay v. MerExchange* they discussed the remedy of an injunction as it relates to NPEs. A NPE may not meet the typical four-part test for an injunction to be applied, since they are not producing a competitive product.<sup>56</sup> There is no equitable ground for the NPE to stand on. Instead, they may only be able to receive monetary damages but the court does not decide the question.<sup>57</sup> Mark Lemley, a law professor at Stanford, has even questioned whether or not universities are patent trolls when asking for injunctions.<sup>58</sup>

An injunction, which restricts someone from practicing an invention, goes against the goals of a university, which are to further the advancement of technology. “In some cases, the absence of irreparable harm, adequacy of legal remedies, balance of hardships, and public

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<sup>53</sup> eBay, *supra* note 47.

<sup>54</sup> Lee, *supra* note 1, at 59.

<sup>55</sup> KIMBERLY MOORE, ET AL. PATENT LITIGATION AND STRATEGY (West Academic Publishing, 4<sup>th</sup> ed. 2013).

<sup>56</sup> eBay, *supra* note 47.

<sup>57</sup> *Id.*

<sup>58</sup> Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008).

interest may counsel against granting an injunction, and ongoing royalties may be sufficient to compensate the university for the infringement.”<sup>59</sup> The remedy of injunctions cannot be abolished for all NPE held patents, however. If injunctions were abolished for all NPEs, others wishing to use the patent may never try to negotiate in good faith with the patent holder. They would instead just practice the invention knowing that the worst outcome is a royalty.

## **Part II: Universities and Their Interactions with Intellectual Property**

It is important to discuss universities and their IP rights when discussing FF inventions. Universities through their employees create many FF inventions.<sup>60</sup> The federal government’s \$150 billion plus R&D budget is primarily funneled through universities.<sup>61</sup> Universities see patents “as a necessary conduit for transferring federally funded technologies to the private sector for commercialization.”<sup>62</sup> Thus, universities are a vital part of how FF inventions become commercial products.

The purpose of a university is to foster education. “[P]ublic service is at the heart of why universities emerged in the public sphere.”<sup>63</sup> “Universities must also promote the dissemination of knowledge through publication, education, basic/non-commercial innovation, healthcare, non-scientific scholarship, and more.” Jacques Loed of the Rockefeller Foundation once stated, “[I]f the institutions for pure science go into the handling of patents I am afraid pure science will be

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<sup>59</sup> Lee, *supra* note 1, at 83.

<sup>60</sup> *McElmurry v. Ark. Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993) (Wherein the Court discussed Common law shop rights provide that an employer is allowed to use an invention patented by one or more of their employees while working for the employer without liability of infringement); *see also* Stanford, *supra* note 14.

<sup>61</sup> Robert E. Litan & Lesa Mitchell, *A Faster Path from Lab to Market*, HARVARD BUS. REV. Jan.-Feb. 2010; *see also* Rooksby, *supra* note 8, at 347 (Where he discusses “respondents at public universities are more sensitive to a defendant’s political influence than are respondents at private universities, to a statically significant degree.”).

<sup>62</sup> Lee, *supra* note 1, at 32.

<sup>63</sup> Rooksby, *supra* note 11, at 316.

doomed.”<sup>64</sup> Patent policy at universities was originally to “serve the public interest” and to ensure “the public could obtain [inventions] at reasonable prices.”<sup>65</sup> Universities use of patents should be for the benefit of the public.

### **A. The Bayh-Dole Act**

Scientific advancement is vitally important to society. “Key technological advances - - from the mass production of penicillin to the Manhattan Project - - helped win [World War II] and revealed to policymakers the importance of large-scale science funding.”<sup>66</sup> Federal funding, prior to 1980, was provided to promote scientific advancement by varying agencies within the federal government. Each agency had its own approach; agencies, such as the National Institute of Health (NIH), kept title to the FF invention and others let the recipient of federal funding take title.<sup>67</sup> Society has promoted technological advances through federal funding for decades.

Some commentators believe funding of the invention should be the only incentive to pursue the product not a patent.<sup>68</sup> However, only 4% of patents created from FF inventions were used to create commercial products prior to the enactment of the BDA.<sup>69</sup> Many governmental agencies were reluctant to give a commercial developer an exclusive license to a patent or the

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<sup>64</sup> Lee, *supra* note 1, at 12 (citing Charles Weiner, *Universities, Professors, and Patents: A Continuing Controversy*, Tech. Rev., Feb.-Mar. 1986, at 33, 35).

<sup>65</sup> *Id.* at 13; *see also* Letter from Mark E. Coticchia, Vice President for Research and Technology Management, Case Western Reserve University to Tobin Smith, Associate Vice President for Federal Relations, The Association of American Universities (January 7, 2010) (*available at* [http://www.aum.net/AM/Template.cfm?Section=Bayh\\_Dole\\_Act&Template=/CM/ContentDisplay.cfm&ContentID=4235](http://www.aum.net/AM/Template.cfm?Section=Bayh_Dole_Act&Template=/CM/ContentDisplay.cfm&ContentID=4235)) [hereinafter *Coticchia*] (Where it discusses that state laws require many not-for-profit organizations, such as universities, assets to be used for proper charitable purposes only).

<sup>66</sup> Lee, *supra* note 1, at 28

<sup>67</sup> Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).

<sup>68</sup> Pusinelli, *supra* note 5, at 411.

<sup>69</sup> *Id.* at 397.

patent right in a FF invention.<sup>70</sup> Most of the technology created from these FF inventions still required large amounts of R&D to create a saleable product.<sup>71</sup> Therefore, many private businesses were reluctant to develop FF inventions any further without patent rights, for fear of competition stealing their design and by-passing the development costs they had incurred.<sup>72</sup>

A change was needed in order to promote the utilization of FF inventions. University collaboration with industry has played a large role in the transformation of FF inventions into commercial products.<sup>73</sup> Universities and industry began to support a legislation change to further promote commercialization of FF inventions in the hands of the government.<sup>74</sup>

Congress passed the Bayh-Dole Act in 1980, to combat the problem of wasted FF inventions. The BDA was created to “promote the utilization of inventions arising from federally supported research or development [and] to promote collaboration between commercial concerns and nonprofit organizations, including universities . . .”<sup>75</sup> A further goal was “to promote free competition and enterprise without unduly encumbering future research and discovery.”<sup>76</sup> The incentive behind the BDA was to get more mileage out of the same amount of federal funding.

The BDA was hailed as “innovation’s golden goose” and was said “spurs job creation”.<sup>77</sup> The BDA gave institutions and inventors the ability to “elect to retain title to any subject

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 393.

<sup>72</sup> *Id.* at 393.

<sup>73</sup> Mowery, *supra* note 6, at 3.

<sup>74</sup> Peter Lee, *supra* note 1, at 64.

<sup>75</sup> 35 U.S.C. §200 (2000).

<sup>76</sup> 35 U.S.C. §202(c)(4) (2011).

<sup>77</sup> *Innovation’s golden goose*, THE ECONOMIST, Dec. 14, 2002, 3, [http://www.economist.com/node/1476653?story\\_id=1476653](http://www.economist.com/node/1476653?story_id=1476653). & Memorandum from Association of University Technology Managers, *The Bayh-Dole Act: It’s working* 1, 1 (available at [http://www.autm.net/AM/Template.cfm?Section=Bayh\\_Dole\\_Act&Template=/CM/ContentDisplay.cfm&ContentID=11603](http://www.autm.net/AM/Template.cfm?Section=Bayh_Dole_Act&Template=/CM/ContentDisplay.cfm&ContentID=11603)).

invention.”<sup>78</sup> The BDA created a structure for determining ownership in FF inventions.<sup>79</sup> It created limited procedural protections, “which expressly give contractors the right to challenge a Government-imposed impediment to retaining title to a subject invention, § 202(b)(4).”<sup>80</sup>

Most FF inventions are performed at institutions such as universities. The institution developing the technology had priority to the invention if elected, then the government, then the actual inventor if everyone else declined.<sup>81</sup> Additionally, “subject invention” as defined in the BDA is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a [federal] funding agreement.”<sup>82</sup> The BDA allows contractors and inventors to retain title to their FF inventions, but does not require them to do so.

A policy behind the BDA was to give universities an ownership interest, the patent right, in FF inventions to provide an incentive to commercialize the invention.<sup>83</sup> The BDA allowed universities to interact more freely with industry due to their ability to retain rights in inventions.<sup>84</sup> Industry became more willing to collaborate due to the clear chain of title for ownership of FF inventions.<sup>85</sup> “[U]niversities could facilitate the direct interaction between inventors and licensees that is often critical to technology transfer.”<sup>86</sup> The understanding was

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<sup>78</sup> 35 U.S.C. § 202(a) (2011).

<sup>79</sup> Sanjesh Sharma, *The Bayh-Dole Act and Allocation of Ownership Rights in Inventions Arising out of Federally Funded Research*, 23 No. 8 INTELL. PROP. & TECH. L.J. 23, 24.

<sup>80</sup> Stanford, *supra* note 14, at 2191.

<sup>81</sup> *Id.* at 2191.

<sup>82</sup> 35 U.S.C. § 201(e) (2002).

<sup>83</sup> Lita Nelsen, *Identifying, Evaluating, and Reporting Innovative Research Development at the University*, In UNDERSTANDING BIOTECHNOLOGY 25, 26-7 (Gale R. Peterson ed., 1993).

<sup>84</sup> David Roessner ET AL., *The Economic Impact of Licensed Commercialized Inventions Originating in University Research*, 1996-2007, at 7-9 (Sept. 3, 2009) (available at [http://www.bio.org/sites/default/files/BIO\\_final\\_report\\_9\\_3\\_rev\\_2\\_0.pdf](http://www.bio.org/sites/default/files/BIO_final_report_9_3_rev_2_0.pdf)).

<sup>85</sup> Wendy H. Schacht, Cong. Res. Service, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* 13 (Mar. 16, 2012), (available at [http://www.autm.net/Bayh\\_Dole\\_Act\\_Report.htm](http://www.autm.net/Bayh_Dole_Act_Report.htm)).

<sup>86</sup> Lee, *supra* note 1, at 65.

universities would be encouraged by the license revenues to invest money and time into the development of products.<sup>87</sup> The BDA provided a defined path to recover costs associated with bringing the invention from the developmental stage to a commercial product.

The government does not lose out on the FF invention after granting the inventor the patent rights. The BDA contains a provision that allows the government to retain rights in the FF invention. The BDA provides that the funding agencies have “a nonexclusive, nontransferable, irrevocable, paid-up license to practice ... the subject invention.”<sup>88</sup> This protected society’s investment in the FF invention by securing a royalty-free license to practice any such FF invention for governmental purposes, whether they be for military, health or otherwise beneficial to the public.<sup>89</sup> The BDA affects the ability of the public to practice the invention, but not the ability of the government agency that is directly funding the invention.

The BDA has a provision for “March-In” rights. These rights allow the government, in certain circumstances, to “March-In” and grant a license to a patent to a third party when a patentee is refusing to grant a license.<sup>90</sup> Additionally, the BDA can restrict the grant of a patent in FF research from the beginning, but only in “exceptional circumstances.”<sup>91</sup> Declarations of exceptional circumstances, however, have been extremely rare when giving out federal

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<sup>87</sup> Brief of the Nat’l Venture Capital Ass’n as Amicus Curiae in Support of Petitioner at 4, *Bd. Of Trs of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188 (2011) (No. 09-1159).

<sup>88</sup> 35 U.S.C. §202(c)(4) (2011).

<sup>89</sup> Memorandum from Association of University Technology Managers, *The Bayh-Dole Act: It’s working* 1, 1 (available at [http://www.autm.net/AM/Template.cfm?Section=Bayh\\_Dole\\_Act&Template=/CM/ContentDisplay.cfm&ContentID=11603](http://www.autm.net/AM/Template.cfm?Section=Bayh_Dole_Act&Template=/CM/ContentDisplay.cfm&ContentID=11603)) [hereinafter *AUTM*]; Pusinelli, *supra* note 5, at 404.

<sup>90</sup> Pusinelli, *supra* note 5, at 408.

<sup>91</sup> 35 U.S.C. §202(a)(ii) (2011).

funding.<sup>92</sup> Additionally, the NIH has never exercised March-In rights.<sup>93</sup> In the end, the inventor has more rights in FF inventions after the BDA than they did prior.

The BDA requires the inventor to pursue commercialization of the FF invention. The inventor, if they elect to retain title in the FF invention, must take “effective steps to achieve practical application of the subject invention.”<sup>94</sup> The holder of title in the FF invention “must try to develop the invention by making reasonable efforts, under the circumstances, to attract licensees and to license the invention to industry.”<sup>95</sup> The licenses given out usually require “due diligence” and “performance milestones” to ensure the FF invention is being developed.<sup>96</sup> The meaning of this provision has yet to be fleshed out by the courts. It could eventually play an important role in protection against patent trolls.

### **B. The Impact of the Bayh-Dole Act**

Determining the impact of the BDA is an incredibly difficult task. The BDA is using the patent system as an incentive, whose impact is hard to determine. When determining the impact of the BDA, you must consider the measure used for nuances and errors it may contain. Further frustrating the determination is how rapidly technology has advanced since the inception of the BDA. Trying to measure the impact of the 30+ year old BDA is a difficult task.

The BDA may have affected patents filed for FF inventions. In 1980, the federal government held approximately 28,000 patents from FF research and fewer than 5% were

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<sup>92</sup> Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66-SPG LAW & CONTEMP. PROBS. 289, 294 (2003).

<sup>93</sup> Rai, *supra* note 92, at 294.

<sup>94</sup> 35 U.S.C. § 203 (a)(1) (2011).

<sup>95</sup> *Licensing Technology from Universities*, Executive Legal Summary 426, EXECLSUM 426 (2014) [Hereinafter *Execlsum*].

<sup>96</sup> Execlsum, *supra* note 95.

licensed to industry for development into commercial products.<sup>97</sup> Universities, a large recipient of federal funds, only held 264 patents in 1979 and by 1997 universities held 2,436 patents.<sup>98</sup> During that same time period, patenting applications in general increased at one fifth of the rate of university held patents.<sup>99</sup> A factor frustrating the determination of the BDA's impact is university patents were already significantly on the rise at the time of the enactment.<sup>100</sup> The impact of the BDA on university patenting is unclear.

During the enactment of the BDA there were "several other developments of great importance for the growth of the U.S. university patenting and licensing."<sup>101</sup> For instance, the U.S. Patent and Trademark Office began granting broader claims to cover new types of artifacts.<sup>102</sup> Additionally, universities had limited technology transfer knowledge at that time.<sup>103</sup> Further, their patenting activities were already increasing due to expanded activities in the biotechnology field.<sup>104</sup> University owned patents increased since the inception of the BDA, but there is a lack of hard evidence linking the two.

Patents generate massive income for universities. The income has led to many institutions with little knowledge of patents to begin patenting their inventions under the BDA.<sup>105</sup> In 2011, universities held 4,700 issued patents and received over \$2.5 billion in patent related income.<sup>106</sup>

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<sup>97</sup> AUTM, *supra* note 89, at 3.

<sup>98</sup> Rai, *supra* note 92, at 292.

<sup>99</sup> *Id.* at 292.

<sup>100</sup> Mowery, *supra* note 6, at 3.

<sup>101</sup> *Id.* at 5.

<sup>102</sup> *Id.* at 7.

<sup>103</sup> Nelsen, *supra* note 83, at 26.

<sup>104</sup> Mowery, *supra* note 6, at 3.

<sup>105</sup> *Id.* at 6.

<sup>106</sup> Assoc. of Univ. Tech. Managers, U.S. Licensing Activity Survey Highlights FY2011 1, at 2-3 (2012) (available at [http://www.autm.net/AM/Template.cfm?Section=FY\\_2011\\_Licensing\\_Activity\\_Survey&Template=/CM/ContentDisplay.cfm&ContentID=8731](http://www.autm.net/AM/Template.cfm?Section=FY_2011_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=8731)).

In the year prior, universities spent \$61.2 billion on R&D and the federal government picked up 61% of the tab.<sup>107</sup> Universities are receiving large amounts of patent related income, nevertheless they may be spending more on R&D.

The BDA has fostered many new start-ups companies. Specifically, “spin-off” companies from universities are being formed.<sup>108</sup> The companies can license the technology from a university and develop commercial products incorporating the technology. However, most of the interaction between industry and universities “has not involved patenting and licensing.”<sup>109</sup> From 1980 to 2008, 6,652 startup companies were formed as a result of university FF research.<sup>110</sup> Of these companies, 72% had their primary place of business in the same state as the university they were licensing technology from.<sup>111</sup> Strong connections between universities and industry have led to more commercial products.

### **C. Universities Assimilating Into the Commercial World**

Since the implementation of the BDA, more FF inventions at universities have been patented. The BDA encourages universities to conduct systematic review of laboratory work in order to assess its value as an IP asset.<sup>112</sup> This work in the past may not have been reviewed for patenting, since patents from FF inventions were not as easy to obtain prior to the BDA. Universities have become more akin to a commercial entity striving to extract profits from its

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<sup>107</sup> Almanac of Higher Education: University Research-and-Development Spending Financed by the Federal Government, FY 2010, Chron. Higher Educ. (2012), (available at <https://chronicle.com/article/University/133233>).

<sup>108</sup> AUTM, *supra* note 89, at 1.

<sup>109</sup> Mowery, *supra* note 6, at 2.

<sup>110</sup> Vicki Loise & Ashley J. Stevens, *The Bayh-Dole Act Turns 30*, 2(52) SCI TRANSL MED Oct. 6, 2010, at 52cm27.

<sup>111</sup> Loise, *supra* note 110, at 52cm27.

<sup>112</sup> Lee, *supra* note 1, at 37.

assets.<sup>113</sup> Since the change in focus, the “research culture” has changed and universities are shying away from sharing their results.<sup>114</sup>

Not every university is looking to extract profits from their patents. In contrast, some have used their control of patents to infuse the commercial world with some of their goals. Universities have been using licenses to “‘push’ certain noncommercial, academic norms into the marketplace.”<sup>115</sup> Universities’ licensing provisions “may also reflect the perceived needs of a university attempting to balance public interest with commercializing the results of its professors’ research.”<sup>116</sup>

For example, researchers at the University of Toronto patented a method of making insulin.<sup>117</sup> Eventually, the university widely licensed the patent and then used it as “a tool to discipline the industrial world, to organize the distribution and use of the new drug, and to guarantee its accessibility.”<sup>118</sup> Some universities want to “ensure product safety, prevent patent piracy, and disseminate technologies widely to the public.”<sup>119</sup> University patents can be used to serve the public good.

University inventions cannot solely be dedicated to the public. It has been said that doing so is “the more efficient way to do science – and maybe the more honorable way.”<sup>120</sup> Further, when looking at cases such as *Association of Molecular Pathology v. Myriad Genetics*, “It seems hard to argue that quicker and cheaper access to this information about one’s own genetic

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<sup>113</sup> Rooksby, *supra* note 8, at 357.

<sup>114</sup> Mowery, *supra* note 6, at 1.

<sup>115</sup> Lee, *supra* note 1, at 46.

<sup>116</sup> *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1321 (Fed. Cir. 2009).

<sup>117</sup> Maurice Cassier and Christiane Singing, *Patenting in the Public Interest; Administration of Insulin Patents by the University of Toronto*, 24 HIST. & TECH. 153, 155 (2008).

<sup>118</sup> Cassier, *supra* note 117, at 156.

<sup>119</sup> Lee, *supra* note 1, at 20.

<sup>120</sup> Rooksby, *supra* note 11, at 317 (citing Dan Morell, *Jay Bradner*, THE ATLANTIC, Nov. 2012, <http://www.theatlantic.com/magazine/archive/2012/11/jay-bradner/309122/>).

disposition would not plant itself firmly in the public interest.”<sup>121</sup> University research can be crucial for advancing science and maintaining the United States’ competitive edge.<sup>122</sup> As such, it is important not to remove an incentive for a university to perform research.

It is believed that universities may not be able to risk as much of their assets as a commercial firm.<sup>123</sup> Universities must take their own goals into mind. They have been criticized for trying to patent foundational research processes.<sup>124</sup> This criticism could lead to potential donors restricting money or changing hiring practices.<sup>125</sup> As NPEs, universities should not have to worry about keeping commercial competition out of the market. They should only be concerned with recovering their costs and funding further research.

The public holds universities to a higher standard, even though they have become similar to commercial entities. However, as Professors Henry Etzkowitz and Andrew Webster have said “[S]cience and property ... have been made contingent upon each other through the concept of ‘intellectual property rights.’”<sup>126</sup> Commercialization of inventions has become part of a

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<sup>121</sup> Rooksby II, *supra* note 11, at 316.

<sup>122</sup> AUTM, *supra* note 89, at 1.

<sup>123</sup> Coticchia, *supra* note 65, at 3.

<sup>124</sup> Lee, *supra* note 1, at 41 (Discussing Columbia University’s attempt to extend exclusivity over cotransformation, a process for inserting exogenous DNA into a host cell to produce particular proteins. Harvard, MIT, and the Whitehead Institute for Biomedical Research received criticism for a broad patent over the NH-kB cell-signaling pathway, which has been linked to a wide range of diseases).

<sup>125</sup> Dennis Crouch, *Although “without tact”, Micron’s retaliatory decision to stop hiring University of Illinois Graduates is not Illegal*, Patentlyo, (April 11, 2013) (available at <http://patentlyo.com/patent/2013/04/although-without-tact-microns-retaliatory-decision-to-stop-hiring-university-of-illinois-graduates-is-not-illegal.html>) (citing Letter from Micron’s hiring coordinator to University of Illinois engineering professors (Where they state “Because Micron remains a defendant in a patent infringement lawsuit that UIUC filed against Micron in Federal court in Illinois on December 5, 2011, effective immediately, Micron will no longer recruit UIUC students for open positions at any of Micron’s world-wide facilities”)).

<sup>126</sup> HENRY ETZKOWITZ & ANDREW WEBSTER, *Science as Intellectual Property*, in HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES 480, 480-81 (Sheila Jasanoff, Gerald E. Markle, James C. Petersen & Trevor Pinch eds., 1995).

university's goals. Former Duke University President Terry Sanford "Once noted that 'universities should do all that is reasonably possible to earn returns on inventions, and should not be timid in making prudent business arrangement to assure the largest fair return.'"127 The character of a university is changing, and with that change, the laws governing them must change.

Universities are becoming more and more active in litigation. In the past they have been "hesitant to take assertive posture in patent enforcement actions."128 The hesitation occurs when they balance their IP rights versus their core goals of not alienating donors, not upsetting political ties to defendants, or undermining their public-service values.129 These goals have not stopped all litigation, however. Professor Jacob Rooksby has compiled a list of patent suits filed by universities between January 1, 2009 and December 31, 2010.130 He has found that 33 universities had filed 57 separate patent infringement suits.131 Universities are asserting their patents and enforcing their rights.

#### **D. Technology Transfer Offices**

Technology transfer offices (TTOs) have become the IP hubs for most universities. "[U]niversity ... [TTOs] have demonstrated their ability to enter into all varieties of arms-length agreements without external intervention."132 TTOs were created to promote university commercial activities; some argue to derive revenues from those activities.133 They exist in order

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<sup>127</sup> Lee, *supra* note 1, at 39 (citing Terry Sanford, *The University and Technology: New Paths and New Perspectives*, in 1 *The Law of Business and Licensing: Licensing in the 1980s* 1-63, 1-67 (Robert Goldscheider and Tom Arnold eds., 1989).

<sup>128</sup> Rooksby, *supra* note 8, at 316.

<sup>129</sup> *Id.* at 318.

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 330.

<sup>132</sup> *Id.* at 319.

<sup>133</sup> Litan, *supra* note 7, at 1.

to take the research created within the university and turn it into a useful product with the help of a private partner.<sup>134</sup> Over 3,000 universities have TTOs that generate over \$1 billion in royalties.<sup>135</sup> These offices are an example of the university's split personality. On the one side you have Dr. Jekyll, who protects the public interest. On the other side is Mr. Hyde, the TTO, who may act as an in house PAE.

TTOs have an unclear goal. It has been said TTOs exist to "benefit society."<sup>136</sup> However, "The university technology transfer officials who draft agreements for the transfer of research materials tend to see their primary job as bringing licensing revenue into the university."<sup>137</sup> TTOs at most universities are not profit centers; in converse, they actually "lose money."<sup>138</sup> The fact that they lose money gives support to the argument that TTOs are not created to generate revenue and may benefit society.

TTOs typically operate as "merely a broker" between the inventor and the licensee.<sup>139</sup> This is not the case at every university; each office may operate drastically different and have varying levels of effectiveness in licensing IP.<sup>140</sup> TTOs primary power resides in the university owned IP and they should have similar goals of benefiting society.

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<sup>134</sup> Letter from Arundeeep S. Pradhan, President, Association of University Technology Managers to Esther Lee, Department of Commerce 1 (January 6, 2010) (available at [http://www.autm.net/AM/Template.cfm?Section=Bayh\\_Dole\\_Act&Template=/CM/ContentDisplay.cfm&ContentID=4234](http://www.autm.net/AM/Template.cfm?Section=Bayh_Dole_Act&Template=/CM/ContentDisplay.cfm&ContentID=4234)) [Hereinafter *Pradhan*]; see also Krief, *supra* note 15, at 726 (discussing Opponents to TTOs that they May clog the patent system. As there may be too many TTOs to license from in order to create a product. Krief responds "the large risks of commercialization in the biotechnology industry to license broadly as a method for reducing risk. Licensing to hedge risks makes sense because once a firm becomes competent in pursuing one avenue of development, the firm may have difficulty keeping track of other potential avenues).

<sup>135</sup> Execlsum, *supra* note 95.

<sup>136</sup> Pradhan, *supra* note 134, at 2.

<sup>137</sup> Rai, *supra* note 92, at 306.

<sup>138</sup> Pradhan, *supra* note 134, at 2.

<sup>139</sup> Larena, *supra* note 44, at 1414.

<sup>140</sup> Pradhan, *supra* note 134, at 2.

### **Part III. Attempting to Turn Profits Back Into Products**

When striving to create an improved law or rule to fix a problem, the answer should be as clear as possible. “The lawyer's greatest weapon is clarity, and its whetstone is succinctness.”<sup>141</sup> The approaches proposed to enhance the BDA so far would not increase its clarity nor enhance its goals. When trying to fix a problem the approach should not cloud the law with uncertainty.

There can be no doubt that the BDA has had an impact on the dissemination of technology, development of commercial products and the progress of the arts and sciences. Its enactment has changed the landscape of FF inventions. However, FF inventions are still being underused and may be blocking future research. Some recent developments and proposals for changes to the BDA to increase its effectiveness are discussed below.

#### **A. Protecting Patent Rights Obtained During Development**

*Stanford v. Roche* was a monumental decision that has been said to further cloud the patent ownership waters. Some believe *Stanford v. Roche* will “hinder the relationships between universities and private entities.”<sup>142</sup> This would be in stark contrast to the goals of the BDA, which were to create a clear ownership framework. However, this decision, as will be discussed, is currently in line with the BDA and will promote further collaboration between the universities and private entities in creating products.

In *Stanford v. Roche*, a Stanford researcher was working on a FF project at Stanford and a similar project at Cetus (Eventually bought by Roche). In order to use Cetus’s facilities, the researcher signed an agreement that any research he did at their facility would belong to Cetus.<sup>143</sup> Cetus was responsible for the upkeep of their facility, not Stanford. The researcher performed

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<sup>141</sup> Judge E. Barrett Prettyman.

<sup>142</sup> Ashlie Depinet, Comment, *The Public is Paying Twice: How Stanford v. Roche undermines the Congressional Intent of the Bayh-Dole Act*, 41 CAP. U. L. REV. 729 (2013).

<sup>143</sup> Stanford, *supra* note 14.

work on better HIV tests at the university and eventually at Cetus.<sup>144</sup> The researcher wanted to learn the advanced Polymerase Chain Reaction (PCR) techniques that Cetus was using.<sup>145</sup> He began to learn the techniques at their facility after executing an assignment giving Cetus rights to any invention he created while working there.<sup>146</sup> Eventually, Stanford filed patents for the HIV tests, under the BDA.<sup>147</sup> Cetus began making the HIV detection kits and Stanford filed suit against their use believing the university had title to the invention because their employee had created the invention.<sup>148</sup>

The court held that Stanford did not have superior title by virtue of the BDA and the rights conferred by the BDA do not automatically override any prior assignment an inventor may have made.<sup>149</sup> The court determined that the established patent law precedents confirmed the rights to an invention do belong to the inventor and that the inventor is free to assign those rights.<sup>150</sup> The contract rights were unaffected by the BDA. The researcher was bound to the agreement he had with Cetus. The court further explained

Since 1790, patent law has operated on the premise that rights in an invention belong to the inventor. See, e.g., *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 493, 13 L.Ed. 504. In most cases, a patent may be issued only to an applying inventor, or—because an inventor's interest in his invention is assignable in law by an instrument in writing—an inventor's assignee. See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187, 53 S.Ct. 554, 77 L.Ed. 1114. Absent an agreement to the contrary, an employer does not have rights in an invention “which is the original conception of the employee alone,” *id.*, at 189, 53 S.Ct. 554; an inventor must expressly grant those rights to his employer, see *id.*, at 187, 53 S.Ct. 554. Pp. 2194 – 2196.<sup>151</sup>

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<sup>144</sup> *Id.*

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

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> Stanford *supra* note 14.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.* at 2190.

This decision emphasizes to industry that they will still have patent rights in inventions when university employees use their facilities. Further, “It is consistent with existing provisions of the Patent Act that state the inventions belong to the inventors who conceive and reduce them to practice.”<sup>152</sup> Each inventor has the ability to assign their patent rights. That assignment, according to the Court in *Stanford v. Roche*, will still be valid since the patent rights revolve around the inventor and not around the inventor’s employer.

The BDA was created to promote collaboration between universities and private industry to fully commercialize FF inventions into products. If every university had superior rights to FF inventions, industry would not want to invest in the development of the FF invention for the fear of losing any rights they may obtain. Industry would be without an incentive and would not be able to recoup their costs of development if a university had a superior right in a FF invention, even if there was a contract. The BDA was not created to give superior rights to any particular inventor; it was created to promote commercialization of FF inventions.

“The [Bayh-Dole] Act's disposition of rights does nothing more than clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor.”<sup>153</sup> *Stanford v. Roche* is in line with the BDA and has strengthened its goals. If Congress wanted to change established patent law with the BDA and give universities a higher priority it would have “said so clearly.”<sup>154</sup> The only outcome from this decision will be universities revising their contracts with employees and industry. The BDA still maintains its framework of ownership after *Stanford v. Roche* and is enhanced by it.

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<sup>152</sup> Sharma, *supra* note 79, at 27.

<sup>153</sup> *Stanford*, *supra* note 14, at 2190-1.

<sup>154</sup> *Id.* at 2191.

## B. Restructuring TTOs

Universities receive large amounts of federal funding for R&D. The university's IP hub, the TTO, needs to be considered when looking to improve the BDA. Litan and Mitchell have argued that that to enhance the effectiveness of the BDA a university-inventor should be able to choose his or her licensing agent.<sup>155</sup> The motive behind who controls FF inventions at universities may affect the BDA's impact.

It has been argued that TTOs are not as effective as they can be. Even though the NIH has increased its federal funding, the number of drugs approved by the FDA are on a downward trend.<sup>156</sup> FDA approval levels spiked up to record levels in 1996 and there is some evidence linking the subsequent drop to inefficient TTOs.<sup>157</sup> However, the link is disputed.<sup>158</sup> Additionally, the Congressional Budget Office explains the sudden spike of approvals and then sudden decline as a result of an increase in the FDA's budget that enabled it to clear its backlog of drug-approval applications.<sup>159</sup> In the end, no matter the cause, new drug approvals have been trending downward since 1996.

TTOs may be restrictive to FF inventions. "Inventive faculty members are hostage to their [TTO], regardless of its efficiency or contacts." TTOs "generate less licensing revenue for the university than the cost of their operations."<sup>160</sup> Additionally, they are normally short staffed

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<sup>155</sup> Litan, *supra* note 7, at 2.

<sup>156</sup> *Id.* at 2.

<sup>157</sup> Coticchia, *supra* note 65, at 2.

<sup>158</sup> *Id.* at 2.

<sup>159</sup> *Id.* at 2. (citing *Research and Development in the Pharmaceutical Industry*, Congressional Budget Office (2006)).

<sup>160</sup> Letter from Bob Litan and Lesa Mitchell, The Kauffman Foundation to Esther Lee, Department of Commerce 1, 2 (August 17, 2009) (available at [http://www.autm.net/AM/Template.cfm?Section=Bayh\\_Dole\\_Act&Template=/CM/ContentDisplay.cfm&ContentID=4233](http://www.autm.net/AM/Template.cfm?Section=Bayh_Dole_Act&Template=/CM/ContentDisplay.cfm&ContentID=4233)) [Hereinafter *Kauffman*].

and underfunded due to operating at a loss.<sup>161</sup> This has led to many professors standing in line, taking a number and waiting their turn.<sup>162</sup> The attention individual inventors are getting is lacking in universities. Short staffing and lack of intimacy with inventors can cripple a TTO's effectiveness.

The relationship between a university's inventors and their TTO is of utmost importance. "[T]echnology transfer works best when faculty have a strong, ongoing relationship with their universities technology transfer office."<sup>163</sup> If an inventor does not get along with or is unengaged with their TTO, the FF invention can suffer. Inventors who have a FF invention worth commercializing may "be ignored or discouraged," while TTOs will concentrate on the inventions they believe are the most important.<sup>164</sup> Thus, society may lose when FF inventions are put on the shelf by a TTO instead of commercialized.

University-inventors faced with an ineffective TTO are forced to use other means. If they want their FF invention to become commercialized they will have to use the "back door."<sup>165</sup> In this instance, the inventor will not tell the university or the government sponsor about their FF invention and instead will proceed to their own agent, "[W]hich a sizeable minority of the faculty already do."<sup>166</sup> Back door inventions are still not effective, as an inventor will have to minimize their communication with potential partners to ensure they do not tip-off a university to their activities.<sup>167</sup> There are currently no good solutions to an ineffective TTO.

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<sup>161</sup> Litan, *supra* note 7, at 2.

<sup>162</sup> *Id.* at 2.

<sup>163</sup> Pradhan, *supra* note 134, at 3.

<sup>164</sup> Kauffman, *supra* note 160, at 2.

<sup>165</sup> Larena, *supra* note 44, at 1419.

<sup>166</sup> *Id.* at 1419; Kauffman, *supra* note 160, at 3.

<sup>167</sup> Kauffman, *supra* note 160, at 3.

Litan and Mitchell argue the best alternative to inventors being stuck with their TTO is to give university-inventors a right to pick the licensing agent of their choice, the free market approach.<sup>168</sup> “It bears emphasis that the right to choose an agent is and would remain independent of the ownership of the IP, which would remain with the university.”<sup>169</sup> The inventors, almost always, understand their inventions the best and understand the path to commercialize them and/or find the optimal partners to help out with the inventions.<sup>170</sup> The inventor should be able to commercialize inventions sitting idle in TTOs.

The free market approach would not destroy TTOs altogether, but instead it would create competition. It would allow university-inventors the ability to choose a TTO from another university or a private agent. “A free market would also most likely lead university [TTOs] to specialize or turn to outside agents with the appropriate expertise.”<sup>171</sup> It may also lead to universities dropping their TTO altogether if they are not worthwhile to operate.<sup>172</sup> With the free market approach universities would still receive revenue generated from the IP.<sup>173</sup> The university would be free to determine what is best for them. This would allow efficient TTOs to help promote inventions from inventors who were being underserved by their own TTO.

Moreover, it is undeniable that universities, as with any other company, compete for the top employees. It is argued that universities would not want to have inefficient TTOs as it would

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<sup>168</sup> *Id.* at 3.

<sup>169</sup> *Id.* at 4.

<sup>170</sup> Larena, *supra* note 44, at 1414.

<sup>171</sup> Litan, *supra* note 7 at 3; *see also* Kauffman, *supra* note 160, at 4 (“[M]ore competition in the technology licensing market should generate a triple “win” outcome”).

<sup>172</sup> Litan, *supra* note 7, at 3.

<sup>173</sup> Kauffman, *supra* note 160, at 1 (Discussing the university will not lose out on profits created from the IP. The typical contract between universities and their faculty usually specifies how “any royalties or other revenues earned from this IP are shared.” Therefore, even without their own TTO they will be able to receive licensing revenues created from federally funded inventors. The university would still have to pay outside agents, however TTOs generally lose money so their situation should be no different).

be a barrier to achieve the best faculty.<sup>174</sup> Opponents of this approach argue universities would be at a disadvantage if TTOs were inefficient at commercializing inventions since potential employees would be deterred.<sup>175</sup> However, the argument actually points to the free market approach as beneficial. It is true that a university with an inefficient TTO would deter prospective employee, but if their employees had the option of using any TTO, then TTOs would not even be a factor when deciding employment. The faculty member would be able to use any TTO they prefer.

Another argument by opponents of the free market approach is that many “inventions have limited, if any, commercial value.”<sup>176</sup> Moreover, “The most time-consuming aspect of commercialization occurs after the license is signed.”<sup>177</sup> These inventions require more funding from the university to get it to a level where commercial investment is appropriate. Nevertheless, TTOs usually lack the resources to properly negotiate and monitor licenses for further development of the invention.<sup>178</sup> However, inventions that on their face do not appear to be commercially viable would not be picked for commercialization by the TTO anyways.<sup>179</sup> Regardless of the level of commercial value, TTOs are limiting inventions that may be developed for society’s use.

Another counter argument to creating a free market for TTOs has been argued by the Association for University Technology Managers (AUTM) and their members. They have said “To turn decisions regarding the disposition of University assets over to individual faculty

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<sup>174</sup> Coticchia, *supra* note 65, at 3.

<sup>175</sup> *Id.* at 3.

<sup>176</sup> *Id.* at 4.

<sup>177</sup> Pradhan, *supra* note 134, at 2.

<sup>178</sup> Larena, *supra* note 44, at 1416.

<sup>179</sup> Coticchia, *supra* note 65, at 4.

members . . . would not only be unenforceable, but also violate state not-for-profit laws.”<sup>180</sup>

However, this is not the case as the assets would still be controlled by the universities’ contract with the individual inventor.<sup>181</sup> The free market approach does not change who owns the revenues generated by the IP.

Fundamental research should be about “Publication and dissemination of research results.”<sup>182</sup> Some believe that with unregulated TTOs there will be more of an incentive to patent fundamental inventions. TTOs are believed to decline to patent “fundamental research tools,” instead they facilitate their dissemination and many “retain research exemptions when licensing their technology to others.”<sup>183</sup> This argument may have worked, except for the cases where the University of Utah held the patents for the BRCA1 and BRCA2 gene, then exclusively licensed it, or where the University of Toledo patented insulin, along with many other cases.<sup>184</sup> In the end, TTOs are supposed to promote patents and licenses with commercial partners to generate revenue, not the commercialization of products.

University-inventors have different goals than TTOs. Professors Rai and Eisenberg have argued that professors care more about the “true science of dissemination” than a TTO.<sup>185</sup> It has been said that professors used to be skeptic of patents due to “[S]cientific norms prioritizing

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<sup>180</sup> Pradhan, *supra* note 134, at 2.

<sup>181</sup> Another argument is proposed that it will harm the charitable goals of the university. “To award control over university inventions to individual faculty members would effectively transfer the benefit of such charitable funds from universities to private individuals in contravention of numerous long-standing tax laws and regulations.” Coticchia, *supra* note 65, at 3. They are arguing that since most universities are non-profit this may change that status. There is no difference if the money is coming in through an inside TTO or an outside TTO. The funds coming in are still counted as income.

<sup>182</sup> Coticchia, *supra* note 65, at 3.

<sup>183</sup> Lee, *supra* note 1, at 44-5.

<sup>184</sup> Cassier, *supra* note 117; *see also* Pathology, *supra* note 50.

<sup>185</sup> Rai, *supra* note 92.

communal sharing over individual property rights.”<sup>186</sup> Jonas Salk, who developed the Polio Vaccine at the University of Pittsburgh, did not patent his invention and instead stated, “Who owns my polio vaccine? The people! Could you patent the sun?”<sup>187</sup> Historically, university-inventors are more concerned with dissemination than patenting.

University-inventors, however, are not immune to self-interest. University-inventors may move frequently between universities and industry.<sup>188</sup> This may lead to them preferring to patent one invention while not another, or to pursue extra patent protection. These decisions could all be guided by future employment opportunities. Since the inception of the BDA, professors have become more receptive to patents and commercializing their inventions.<sup>189</sup> Whether a TTO or professor controls the course of action, there is no safeguard to protect against one’s own self-interest of survival.

To truly promote commercialization of products there needs to be an intermediate party (mediator) between the university and society (the checkbook). TTOs, currently, do not fill this role. University-inventors may be able to if allowed to use the free market approach to TTOs. They may not share universities interests, but that is superfluous as the core of federal funding is to give a benefit to society.<sup>190</sup> The interests of the university should be secondary to that of the commercialization of FF inventions and dissemination of the information learned from the

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<sup>186</sup> Lee, *supra* note 1, at 10; *see also* Richard R. Nelson. *The Simple Economics of Basic Scientific Research*, 67 J. Pol. Econ. 297, 302 (1959) (Further discussing that prominent scientist are disinterested with the profits and the patent system such as Michael Farady, James Maxwell, Charles Darwin, Louis Pasteur, and Louis Aggasiz. “[S]cientists have long argued for free and wide communication of research.”)

<sup>187</sup> Sara Boettiger & Brian D. Wright, *Open Source in Biotechnology: Open Questions*, INNOVATIONS, Fall 2006, at 45, 48; *see also* *Diamond v. Charkbarty*, 100 S.Ct. 2204, 2208 (1980) (Discussing where you may not be able to patent the sun but “anything under the sun”).

<sup>188</sup> Lee, *supra* note 1, at 48.

<sup>189</sup> *Id.* at 48.

<sup>190</sup> Coticchia, *supra* note 65, at 4.

federal funding. However, the most suited intermediary would most likely be the government. Professor Pusinelli, however, notes them as a costly alternative to regulate patents from FF inventions. A university-inventor would be the most cost effective intermediary between the university and society.

An approach to enhance commercialization of FF inventions would be to allow universities to have unrestricted access to each other's TTOs in a way similar to that proposed by Litan and Mitchell. The system would look for a middle ground between the current restrictive TTOs and a complete free market approach, where inventors use the university as the checkbook. The approach would allow universities better suited to operate a TTO to take on inventions from other universities.

This approach would give the university-inventors some clout when a TTO is deciding whether or not to commercialize their FF invention. In this approach, each inventor should first try their in-house TTO at patenting the FF invention and its eventual commercialization through licensing. Then, if the FF invention is not taken up by the internal TTO within a certain period of time, the university-inventor should be allowed to use any TTO they wish. The TTO would not be the sole source for the inventor. Additionally, the university would be better equipped to monitor their TTO. The university would be able to see if inventions their TTO passed on became successful at another TTO. In this approach any TTO that is effective will not lose any business and it would satisfy all of AUTM's, Mitchell's and Litan's concerns.

This approach would liberalize the unforgiving structure of TTOs. The liberalization of TTOs would allow exceptional ones to help more FF inventions get into the public space. It would also force underperforming TTOs to either improve or close, as they would then have

competition. This would provide an incentive for universities to keep an effective TTO if they want to keep their FF inventions close.

Further, an incentive for a TTO to take on the responsibility of the FF invention from another university would need to be created. Some inventions that are patented now may be less significant and not recover costs.<sup>191</sup> The first university where the university-inventor works should not have to cover the expenses of another university's TTO. The incentive for the second TTO should be a cut of the royalties or license. In this approach, no upfront costs would be assessed on the first university by a university-inventor with an insubstantial FF invention. These FF inventions would most likely be rejected by all other TTOs as they would be judged on their commercial potential. The first university would not lose any money as they still own the patent rights and instead may be able to receive royalties they otherwise would not have been able to receive.

TTOs may believe they cannot survive in a competitive environment and will no longer be able to operate. However, "productive policy changes that benefit society as a whole should not be stillborn because of opposition of small interest groups or self-interested parties."<sup>192</sup> The BDA was not created to foster TTOs. The BDA was created to turn more FF inventions into products. If TTOs stand in the way of products they should be changed or abolished.

### **C. Management of Federally Funded Inventions**

The BDA restricts the universities' ownership of FF inventions. They are not allowed to transfer the patent rights in a FF invention without the government agency's approval, unless the "assignment is made to an organization which has as one of its primary functions is the

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<sup>191</sup> Mowery, *supra* note 6, at 5.

<sup>192</sup> Kauffman, *supra* note 160, at 5.

management of inventions.”<sup>193</sup> This has led to universities creating other corporations, such as the University of Wisconsin’s WARF, or transferring the patents to outside licensing managements companies.<sup>194</sup>

Universities have found a way to exploit the statement in the BDA that provides for the transfer of their inventions to companies whose “primary functions is the management of inventions.”<sup>195</sup> Universities are beginning to transfer their IP to the most notorious PAEs, patent trolls. Additionally, university practices are becoming closer to PAEs in their use of patent enforcement.<sup>196</sup> Many PAEs extract licenses through threats of litigation or litigation itself.<sup>197</sup> Universities are transferring their patents to revenue generating machines that are disinterested in creating products and instead concentrate solely on profits. This is in contradiction to the goals of the BDA, which are to promote commercial products not profits.

An example of a university licensing its technology to a PAE is illustrated in *Eolas Technologies, Inc. v. Microsoft Corp.*<sup>198</sup> In the case the University of California licensed one of their patents to a PAE. The PAE sued Microsoft and obtained a jury award of \$520.6 million and ultimately the University of California obtained \$30.4 million as a settlement.<sup>199</sup> The unsettling part is that almost 50 universities have signed on with the most prominent PAE, Intellectual

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<sup>193</sup> 35 U.S.C. § 202(c)(7)(A) (2006).

<sup>194</sup> Henry Etzkowitz, *supra* note 50, at 386; *see also* Pathology, *supra* note 50.

<sup>195</sup> 35 U.S.C. § 202(c)(7)(A) (2006).

<sup>196</sup> Jaconda Wagner, *Patent Trolls and the High Cost of Litigation to Business and Start-Ups - A Myth?*, MD. B.J., Sept./Oct. 12, 14 (2012).

<sup>197</sup> *See also* Wagner, *supra* note 196, at 12 (“Since 1985, Patent Freedom has identified 560 distinct NPEs with nearly 1,500 subsidiaries and affiliates having 22,000 active patents and 35,000 total patent publications. It found that these NPEs have litigated against 8,000 different operating companies in about 5,700 actions for more than 22,000 events.”).

<sup>198</sup> *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005).

<sup>199</sup> Lee, *supra* note 1, at 43-4.

Ventures.<sup>200</sup> Even more concerning, when universities assign their patent rights to a PAE the deals are harder to track and avoid detection as the university no longer owns the patent, the PAE does.<sup>201</sup> In effect, they get to collect the revenue without getting their name involved with the patent suit. In the end, even if the universities have not assigned their patents to Intellectual Ventures to extract revenue, they are starting to adopt the same business model.<sup>202</sup>

Enhancing dissemination cannot mean asserting a patent with no intentions of turning that patent into a product. The BDA was conceived because many FF inventions were lying dormant and underused. It was not created to allow PAE to use it as a revenue stream without promoting inventions. The PAE could have no intentions of furthering the invention at all and instead only desire profits. The BDA should not give a PAE an exclusive buying power on FF inventions from universities.

Deciding who has a primary purpose for “management of inventions” is not easy to discern.<sup>203</sup> This language in the BDA has only led to further abuse of FF inventions by PAEs and other companies to capitalize on the profits that a patent can generate. The BDA should change the restriction on primary purpose of “management of inventions” to allow industry to be on equal footing with PAEs. There are two different approaches to fix this construct of who can own a FF invention.

The first way would be to further restrict the phrase “primary functions is management of inventions” to include only university owned entities. However, this still may be problematic if TTOs have exclusive rights to the inventions. They can be inefficient and PAE-like themselves,

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<sup>200</sup> Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1, 8 (available at <http://stlr.stanford.edu/pdf/feldman-giants/among-us.pdf>).

<sup>201</sup> Rooksby, *supra* note 8, at 374.

<sup>202</sup> Ewing, *supra* note 200, at 6.

<sup>203</sup> 35 USC §202(c)(7)(a) (2011).

while further restricting the phrase will lead to fewer FF inventions becoming available for public use.

The second way the phrase could be changed would be to eliminate it entirely. In this approach, the biggest abusers of the patent system, patent trolls would not have better footing to acquire the inventions. Any company could also attempt to get the rights in the patent. Further, companies that produce products would be more apt to further develop the technology. Patent trolls should not have an advantage over product producing business when acquiring FF inventions.

To prevent abuse by PAEs, when a patentee is enforcing a patent they should have to affirmatively prove that they have “within a reasonable time taken effective steps to achieve practical application of the subject invention in such field of use.”<sup>204</sup> In an infringement action, the burden should be on the patentee not the infringer to prove this. This would require the PAE to show they started to develop a commercial product or tried to pursue an agreement with a company prior. They would have to prove they were actively seeking collaborators, partners, or manufacturers to help bring their invention to market. Then, an entity would have to prove they were not merely waiting idly by to enforce their rights against others (extortion), who may have never even heard of their patent. In the end a company that does not research new technology or develop new products should not be allowed to extract profits from FF inventions without attempting to commercialize them.

Another problem is there is no automatic right for the government to take title to the FF invention if the BDA is not complied with.<sup>205</sup> To enhance commercialization ,the patent rights

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<sup>204</sup> 35 USC § 203(a)(1) (2011).

<sup>205</sup> *Central Admixture Pharmacy Services, Inc. V. Advanced Cardiac Solutions, P.C.* 482 F.3d 1347 (Fed. Cir. 2007).

should automatically revert to the government agency in the case where the patent rights are not applied to a commercial technology within a certain period of time.<sup>206</sup> The period of time could be extended based on a showing of active development. The companies pursuing patents through the use of the BDA should already be familiar with its provisions requiring efforts to commercialize. This additional requirement should not come as a shock and would give the BDA teeth to lash back at those holding on to the technology solely for profits and not commercialization.

Professor Jacob Rooksby has mentioned that universities having their name on lawsuits can affect proper decisions that will promote further commercialization of FF inventions.<sup>207</sup> Universities are on a slippery slope when pursuing patents and enforcing those patents, especially when they try to seek a remedy from an infringer. Their “disinclinations to enforce their patents through infringement litigation only serve to undermine their research missions in several important ways.”<sup>208</sup> The BDA should be amended to allow universities to transfer the patent rights to industry, not just invention managers. The university would not be required to be on the patent infringement suit if they no longer have rights in the invention. Universities would not have to worry about upsetting political ties if they were not involved in the lawsuits concerning the FF inventions they developed.

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<sup>206</sup> This period of time would have to be researched. But I believe cutting a patent’s lifetime short would be a great incentive to make sure it has commercial use and is not just a sitting time bomb to be enforced some 15 years later after it was issued with no development in between issue and enforcement.

<sup>207</sup> Rooksby, *supra* note 8, at 352 (Interviewee response “Why have this asset if you’re not willing to defend it?”).

<sup>208</sup> *Id.* at 359 (1- wasted resource can be getting money from it. 2- jeopardizes commercial relationships. 3- jeopardizes faculty relationships.).

Courts “have routinely rejected academic exceptionalism,” in the past.<sup>209</sup> Universities do not have a special standard to follow when it comes to IP when acting as any other commercial entity. Moreover, the Court’s implicit message in *Griffith v. Kanamaru* was that if universities avail themselves to the benefits that the patent system offers, then they have to take all the problems created too.<sup>210</sup> If universities can enforce their patents the same as a PAE can, they should not be given a higher right than other businesses.

Universities understand they are not entitled to special treatment. This has caused them to improve their use of patents. They began

Enticing industry with more favorable licensing terms while reducing encumbrances to their ownership of patents, launching new degree programs to prove ‘the kind of education industry is seeking,’ and constructing and updating building in which companies can set up research wings on campus are just a few of the many ways in which universities are realigning their priorities in response to a new financial reality.<sup>211</sup>

Treating universities special can only stifle commercialization of FF inventions. Forcing them to act similar to industry will make them more efficient.

#### **D. Patent Pools as a Limited Research Exemption**

It is argued that universities should not patent experimental uses of a product. The Experimental Use Doctrine (“EUD”) was first constructed in *Whittemore v. Cutter*, where Justice Story said “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments.”<sup>212</sup> However, the EUD did not stand the test of time when Judge Rader obliterated it when he stated, “neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed

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<sup>209</sup> Lee, *supra* note 1, at 51.

<sup>210</sup> *Id.* at 52; *see also* *Griffith v. Kanamaru*, 816 F.2d 624 (Fed. Cir. 1987).

<sup>211</sup> Rooksby, *supra* note 8, at 357.

<sup>212</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

with a particular purpose or intent, such as for scientific experimentation or idle curiosity.”<sup>213</sup>  
“[T]he Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement.”<sup>214</sup>

Patent pools have been proposed as a way to revive the EUD in a limited way.<sup>215</sup> Patent pools have been an approach for industry and government alike to get involved in disseminating technology and creating products. However, their use may be counterproductive to the BDA.

Professor Pusinelli approached patent pools with the hopes of using it to revive the EUD inside of the BDA. His first approach was for all researchers whose work is supported by federal funds to have a limited, royalty-free license to make and use for research purposes all inventions developed with federal funds.<sup>216</sup> The proposed license does not include the right to sell.<sup>217</sup> This would give more access to FF research for those who need access in the short term.<sup>218</sup> He believes this will lead to the only inquiry being whether or not the government funds the research. A fact he trivializes as easily ascertained, as this may not be the case.

Many universities and private companies work on more than one type of project at their location. It is easily ascertained who has federal funding but the extent of the impact of the funding on the entity is harder to discern.<sup>219</sup> For instance, when a university has a research exemption for technology there may be no oversight on what is acceptable use of the

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<sup>213</sup> Pusinelli, *supra* note 5, at 426.

<sup>214</sup> *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352 (Fed. Cir. 2000); *see also* *Madey v. Duke Univ.*, 307 F.3d 1351, 1363 (Fed. Cir. 2002) (The court stated that experimental use was not excused where the use serves “legitimate business objectives, including educating and enlightening students and faculty participating in these projects.”).

<sup>215</sup> Pusinelli, *supra* note 5.

<sup>216</sup> *Id.* at 443.

<sup>217</sup> *Id.* at 447.

<sup>218</sup> *Id.* at 443.

<sup>219</sup> *Larena, supra* note 44, at 1414.

exemption.<sup>220</sup> Professor Pusinelli has said it is hard to determine whether someone is using the technology for research only or trying to design around it.<sup>221</sup> Therefore, policing this exemption would only lead to more litigation and uncertainty in FF inventions.

Professor Pusinelli recognizes another problem.<sup>222</sup> In the case where the technology is only used to research another (i.e. not sold as a good but instead a technique) there would be no recovery to the patent holder. He suggests attaching a fee to the eventual sales from a product produced by using the patented technique.<sup>223</sup> This approach would require hiring extensive amounts of people to determine which technologies the product affected. This would lead to FF inventions becoming time bombs. Patent holders would sit back and wait until an invention was made from a partner and then demand royalties while claiming their technology helped the product. It would be near impossible to ascertain if they used the techniques or not. In the end, it may give patent trolls an even bigger club to use against inventors.

In another approach, the patent pool would require the government to hold the patents for all FF inventions. Then the royalties would get paid into the pool and distributed evenly depending on the contribution of each participant.<sup>224</sup> This would require accounting of each patent's contribution. Further, this approach would be similar to times prior to the BDA,

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<sup>220</sup> What if another unrelated project needs to use the technology? Can a private company then contract the University with the research exemption to use it for them? What if the technology is a research technique itself? How do you recover?

<sup>221</sup> Pusinelli, *supra* note 5.

<sup>222</sup> *Id.* at 448 (Discussing that it is then argued that developing easy to use kits will let patentee's recover their development costs because the kits are easier to use than performing the invention on your own. However, what would stop someone from going around to every kit and remaking and then selling? Pusinelli argues the patent would because then it is for commercial gain. This may not be the case if it was a non-profit. Additionally, the cost of recovery would then have to be minimal since an extraordinarily priced kit would not sell. Contributory infringement may get manufacturer for kits. However if it's only the use then the only active infringer is the user. This may create problems for patentees.).

<sup>223</sup> Pusinelli, *supra* note 5, at 449.

<sup>224</sup> *Id.* at 460.

effectively eliminating individual control of the patent rights. Universities would not be able to transfer the invention from the patent pool and instead would be stuck with a straight royalty for the invention. This may discourage industry, as rights in the FF inventions would be clouded once more. Any costs in commercializing the invention would be harder to recoup, as recovery would be limited to the extent that the entire pool achieves a return.

Moreover, the pooling agreements would not be allowed unless they “contribute to an efficiency-enhancing integration of economic activity among the participants.”<sup>225</sup> Patent pools can restrict the field when the access to the patent pool is limited and where members cannot license out their individual IP.<sup>226</sup> Professor Pusinelli notes the free use of the patented invention in research may eventually result in a negative effect on incentives to develop the patented invention, which would defeat the purpose of the BDA rendering it moot.<sup>227</sup>

The “consensus among those studying the American patent system is to focus on utilitarian approaches.”<sup>228</sup> The BDA is an extension of the patent system and the approach should be similar when studying it. The BDA promotes dissemination of technology into the public space with new products. However, creating patent pools would inevitably clog the system. There would have to be another governmental agency to police the pools. Moreover, the pools themselves would act as barriers to entering the field. Patent pools would not promote the goals of the BDA.

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<sup>225</sup> U.S. DEPT OF JUSTICE & FED’L TRADE COMM’N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (1995) (available at <http://www.ftc.gov/reports/innovation/p040101PromotingInnovationandCompetition>).

<sup>226</sup> Sher, *supra* note 38.

<sup>227</sup> Pusinelli, *supra* note 5, at 447 (He discusses that his proposal presents a problem if a proposed research tool needs further development and there is no way for the developer to recover the costs except through the licensing of the original patent.).

<sup>228</sup> Kieff, *supra* note 15, at 697-8; *see also* Pusinelli, *supra* note 5 (Pusinelli also agrees the patent system should follow a utilitarian approach.).

Patent pools would end up becoming governmentally funded patent trolls. They would extort anyone wanting to enter the field into paying into or becoming a part of their patent pool. Even with the BDA creating more products out of the FF inventions, not every FF invention can be seen as commercial product that actually benefits society. Some inventions probably were better kept on the shelf. Additionally, it would inevitably be unfair to the inventors in the patent pools with inventions generating revenue to share the patents with the rest of the pool, if the others do not generate any revenue. There would have to be some entity to provide an accounting to the group of who used which patents. Overall, patent pools for FF inventions would be similar to the welfare system for bad inventions. Patent pools could not have been an intention of the BDA.

#### **E. Relaxing the “Exceptional circumstances” and “March in Rights”**

Another proposal to further the goals of the BDA is to allow the government more discretion over which FF inventions inventors pursue patent rights on. Professors Rai and Eisenburg have proposed a solution to liberalize the circumstances in which the government may take the patent rights in an invention.<sup>229</sup> They propose a solution of increasing the discretion government agencies have when giving out federal funds. They propose to delete the “exceptional circumstances” language from the BDA and remove the requirement that the government hold March-In Rights in abeyance.<sup>230</sup> The proposal would remove the administrative checks and balances built into the BDA to protect patent owners against pre-BDA hostility towards patents from government agencies. The proposal would effectively eviscerate the BDA, not improve it.

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<sup>229</sup> Rai, *supra* note 92, at 310.

<sup>230</sup> *Id.* at 311.

The proposed changes will bring FF research back to pre-1980.<sup>231</sup> Professors Rai and Eisenburg argue that the times have changed and government agencies will not restrict patenting of FF research to pre-1980 levels, but they do note this is a possibility in the long-term.<sup>232</sup> “While this provision would seem ideally suited to their purpose, [Rai and Eisenburg] note that in fact it is an unwieldy tool.”<sup>233</sup> Professors Rai and Eisenburg offer a modification to the BDA that removes the structure the BDA has created.

To relax the BDA, as suggested, would require the government determining, in advance, which inventions are worthy of patent protection. In other words, the government must predict the future. Even though, there is dictum in *Vitamin Technologists v. Wisconsin Alumni Research Found.* that suggests university “patents should not constrain access to an important discovery with great potential to enhance social welfare,” predicting that potential is not easy.<sup>234</sup> The use of hindsight may not be enough to determine which inventions should have patent protection let alone predicting the future. Sometimes, the potential of a FF invention cannot even be seen as important until years in the future.<sup>235</sup> A commercial entity must undertake a gamble when developing a new product, with sales as unpredictable as the stock market. If you cannot determine what the research will create, you cannot properly decide whether or not to restrict the patent rights to the inventions.

The proposal would also require significant governmental involvement to monitor. The proposal would require 1,000 new employees.<sup>236</sup> Professors Rai and Eisenberg believe, since the

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<sup>231</sup> Pusinelli, *supra* note 5, at 437.

<sup>232</sup> Rai, *supra* note 92.

<sup>233</sup> Pusinelli, *supra* note 5, at 433.

<sup>234</sup> Lee, *supra* note 1, at 27; *Vitamin Technologists v. Wisconsin Alumni Research Found.*, 146 F.2d 941 (9th Cir. 1944).

<sup>235</sup> Rooksby, *supra* note 8, at 328.

<sup>236</sup> Pusinelli, *supra* note 5, at 438.

NIH is drawn from scientists and universities' employees, they are best suited to determine which programs are deserving of patents in FF inventions.<sup>237</sup> This may not be true, as AUTM will argue TTOs are best suited to determine what to do with inventions and others argue that inventors will be.<sup>238</sup> Further, they put forth no reasoning why the NIH has employees that are less prone to promote underuse of FF inventions now, than the pre-BDA era. In any event, the amount of oversight required would frustrate industry as they tried to sort out what IP rights they would have in the invention.

The relaxing of the BDA as proposed by Professors Rai, Eisenburg and Pusinelli would de-incentivize developing FF inventions. Overall, their approaches to fix the BDA are misplaced. Professors Rai and Eisenburg are arguing for “abolition of the BDA not a subtle tuning to effectuate its purpose.”<sup>239</sup> Additionally, neither Professor Pusinelli, nor Rai and Eisenburg’s proposals extend to research tools created with private funds. These tools could be the ones that are the most restrictive to the potential victim. The extension of “‘patentable material’ into the realm of science . . . reflects developments in a much broader set of policies and institutions (notably, in the U.S. Patent and Trademark Office).”<sup>240</sup> Specifically targeting their attack to the BDA would not effectuate their purpose, as noble as it may be. Privately developed inventions would still restrict research. Their approach would be better suited towards a 35 U.S.C. § 101 challenge.<sup>241</sup>

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<sup>237</sup> Rai, *supra* note 92, at 312.

<sup>238</sup> AUTM, *supra* note 89.

<sup>239</sup> Pusinelli, *supra* note 5, at 439.

<sup>240</sup> Mowery, *supra* note 6, at 3.

<sup>241</sup> Rai, *supra* note 92; *see also* Chakrabarty, *supra* note 187.

## Conclusion

When enhancing a law that has brought structure to an area with undefined rights you should not look to dismantle that structure. Most proposals to change the BDA would undermine its structure. It is hard to determine what incentives are needed to drive industry to develop products without stifling further development. However, creating patent pools or limited research exemptions would inevitably clog the system. Additionally, promoting academic exceptionalism in the context of patents should not be allowed. If universities can enforce their patents the same as a PAE they should not be given a higher right than other businesses. The goals of the BDA are to turn FF inventions into commercially available products, not to create profits for the patentee.

Creating commercial products cannot mean asserting a patent with no intentions of turning that patent into a product. When a patentee is enforcing a patent, as a PAE, they should have to affirmatively prove that they have “within a reasonable time taken effective steps to achieve practical application of the subject invention in such field of use.”<sup>242</sup> Adding an automatic right for the government to take title to the FF invention will further promote diligence in creating products with those holding FF inventions, if the BDA is not complied with.

Furthermore, removing universities from lawsuits can let proper decisions be made that will promote further commercialization instead of achieving a university goal. Increasing the options a university-inventor has to use while commercializing their invention will increase the benefit society receives from federal funding. Furthermore, allowing industry to be on equal footing with TTOs and other PAEs can remove universities from the decision making process.

The BDA has had a great impact on FF inventions. Its provisions have not aged well with time as universities have become increasing similar to commercial entities. Repealing the law

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<sup>242</sup> 35 USC § 203(a)(1) (2011).

may undo all the structure it has accomplished and throw FF inventions in a zone of uncertainty.

Ultimately, the provisions of the BDA need to be updated to reflect the current state of the system.