

# DANGEROUS LIAISONS: PATENT LAW AND UNIVERSITY RESEARCH

## I. INTRODUCTION

Taxol.<sup>1</sup> Perhaps no other single invention better embodies the goal of the modern university technology transfer office. The blockbuster drug has generated over \$300 million in licensing revenue for Florida State University,<sup>2</sup> home of the researchers who discovered an artificial method of synthesizing the compound.<sup>3</sup> The university has invested that money, funding other research programs, erecting new buildings, and enhancing faculty salaries.<sup>4</sup> Without the sweeping changes in federal patent policy over the past twenty-five years, however, FSU would not have had such success. For other universities, though, FSU's love affair with patent law may be more dream than reality.

### A. CHANGING LAW SINCE 1980

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<sup>1</sup> Taxol is Bristol-Myers Squibb's trademark for a cancer-fighting substance found in the bark of the Pacific yew tree. *Bd. of Educ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1332 (Fed. Cir. 2003).

<sup>2</sup> Robert Trigaux, *Techies Harness Business Potential*, ST. PETERSBURG TIMES, May 19, 2004, at D1; see also Juana Jordan, *Taxol 'Gravy Train' Gone at FSU*, TALLAHASSEE DEMOCRAT, November 15, 2004, at B1 (citing highest single-year license revenues as \$67 million). Taxol's revenues have fallen significantly because licensee Bristol-Myers Squibb now uses an alternative manufacturing process. Stephen Pounds, *Florida Universities Cashing in on Science*, PALM BEACH POST, June 13, 2004, at F1.

<sup>3</sup> For an overview of Florida State's experience with Taxol, see generally *Taxol Research at FSU*, at <http://www.research.fsu.edu/taxol/discovery.html> (last visited April 19, 2005).

<sup>4</sup> Jordan, *supra* note 2.

In 1980, Congress embarked on a reevaluation of how federal patent laws affect the transition of core research into applied technology. To facilitate that transition, Congress has encouraged interaction between academic research institutions and industry. On the academic side, researchers discover the fundamental science behind all technology.<sup>5</sup> On the industry side, businesses apply that science, creating high-tech goods that benefit society.

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<sup>5</sup> University researchers account for over 50% of basic research conducted in the United States. David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 101 (2001).

In 1980, as the first step in its reevaluation, Congress passed the Bayh-Dole Act, which regulates the ability to patent research conducted with federal funding.<sup>6</sup> Because the federal government funds nearly 90% of university research,<sup>7</sup> patent laws governing innovations developed with federal funds have a pervasive effect on university research. Prior to 1980, federal agencies usually retained patent rights to inventions they funded.<sup>8</sup> Without the right to patent most discoveries, few universities owned patents, preventing Taxol-like windfalls. Meanwhile, federally owned patents idled in bureaucratic obscurity, producing little benefit to the public, the government, or academic inventors.<sup>9</sup>

The Bayh-Dole Act reversed pre-1980 rules and allowed universities to patent inventions created with federal funds.<sup>10</sup> In theory, vesting universities with patent rights gives industry incentive to obtain licenses and develop applied technologies, an

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<sup>6</sup> Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-211, 300-307).

<sup>7</sup> Kenneth Sutherland Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD & DRUG L.J. 453, 457 tbl.2 (1997).

<sup>8</sup> For a comprehensive history of federal ownership of patents, see generally, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996).

<sup>9</sup> Harry Rubin et al., *From Ivory Tower to Wall Street—University Technology Transfer in the US, Britain, China, Japan, Germany, and Israel*, 11 INT'L J.L. & INFO. TECH. 59, 60-61 (2003).

<sup>10</sup> 35 U.S.C. § 202(a) (2000).

incentive lacking under federal ownership.<sup>11</sup> In practice, supporters say the Act has been a tremendous boon to universities, increasing patent portfolios and licensing revenues.<sup>12</sup> Some even credit the Bayh-Dole Act with jump-starting the economic boom of the 1990s and creating the modern biotech industry.<sup>13</sup>

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<sup>11</sup> Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 194-95 (2002).

<sup>12</sup> Rebecca S. Eisenberg & Arti K. Rai, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 292 (2003) (noting increase in university yearly patenting from 264 to 2,436 between 1979 and 1997).

<sup>13</sup> Jeffrey R. Armstrong, *Bayh-Dole Under Siege: The Challenge to Federal Patent Policy as a Result of *Madey v. Duke University**, 30 J. COLLEGE & UNIV. L. 619, 619 (2004).

Not all university research stems from federal funding, though. Private industry has significantly increased funding for university research.<sup>14</sup> For universities, though, patenting innovations jointly created with industry has been a tricky proposition. A 1997 ruling by the Court of Appeals for the Federal Circuit, *OddzOn Products, Inc. v. Just Toys, Inc.*, allowed confidential prior innovations of research team members to invalidate a patent on a later team invention.<sup>15</sup> Having said that information shared among a research team endangers patentability, the decision chilled industry's enthusiasm for university partnerships.

Responding to the decision,<sup>16</sup> Congress passed the Cooperative Research and Technology Enhancement Act (CREATE Act)<sup>17</sup> in 2004. The CREATE Act amended 35 U.S.C. § 103(c) to more clearly define the patentability of inventions in collaborative research situations. More specifically, the amended provision allows research teams to

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<sup>14</sup> See Newberg & Dunn, *supra* note 11, at 193 (“Private companies currently fund about 7% of all university research . . . a dramatic increase in recent years.”).

<sup>15</sup> *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (1997) (holding that confidential information passed between research team members may bar patentability for any new invention created by the team).

<sup>16</sup> 150 Cong. Rec. H10219-02 (November 20, 2004) (statement of Rep. Sensenbrenner) (“[T]he bill responds to the 1997 [*OddzOn*] decision of the Federal Circuit Court of Appeals by clarifying that prior inventions of team members will not serve as an absolute bar to the patenting of the team's new invention.”).

<sup>17</sup> Pub. L. No. 108-453, 118 Stat. 3596 (codified at 35 U.S.C. § 103(c)).

share confidential information without defeating patentability. By having up-front written joint research agreements,<sup>18</sup> universities and their industry counterparts can escape the *OddzOn* trap. More secure patentability prospects should encourage the growth of university–industry research partnerships, the kind of interaction Congress has sought since 1980.<sup>19</sup>

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<sup>18</sup> 35 U.S.C.A. § 103(c)(3) (2004).

<sup>19</sup> 150 Cong. Rec. S7520-05 (June 25, 2004) (statement of Sen. Hatch) (“This act will encourage greater cooperation among universities, public research institutions and the private sector.”).

As *OddzOn* shows, the courts have also actively shaped patent rules that affect academic research institutions.<sup>20</sup> Most importantly, the Federal Circuit restricted the common-law experimental use exception to infringement in *Madey v. Duke University*.<sup>21</sup> After *Madey*, universities (and their researchers) may no longer defend themselves against an infringement claim by relying on either their status as nonprofit, educational institutions or the noncommercial nature of their research.<sup>22</sup> Without this defense, university researchers who use patented technology must purchase licenses or face increased exposure to liability.

Whereas the Federal Circuit in *Madey* restricted a *common-law* exception, the court narrowly construed a *statutory* safe harbor in *Integra Lifesciences I, Ltd. v. Merck KGaA*, now on appeal to the Supreme Court.<sup>23</sup> Both cases restricted infringement

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<sup>20</sup> Courts have decided many important patent questions in recent years that have had an indirect impact on universities as patent owners. See generally, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (discussing prosecution history estoppel); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) (discussing doctrine of equivalents). This paper focuses on laws having more direct impact on university research.

<sup>21</sup> 307 F.3d 1351 (Fed. Cir. 2002). The experimental use exception could fill an entire paper itself. Despite the brief treatment received here, the topic is too relevant to university research to ignore in this paper. For a more thorough treatment see generally, for example, Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001) (arguing for expanded experimental use exception).

<sup>22</sup> See *infra* notes 54-63 and accompanying text.

<sup>23</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *cert. granted sub nom.*

exemptions but to different effect: *Madey* increased academic researchers' exposure to liability, but *Integra* expanded their rights as patentees. In a split decision, the *Integra* panel expressly defended the rights of research tool patentees, many of whom are universities or university employees.<sup>24</sup>

## B. PROBLEMS WITH CURRENT APPROACHES

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Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 823 (2005).

<sup>24</sup> *Id.* at 867.

With so many patent laws touching on academic research, universities and researchers have reason to question how beneficial those laws have been. Critics say the Bayh-Dole Act has had little real effect, merely coinciding with a patenting boom that would have occurred anyway.<sup>25</sup> Although statistics show increased patent numbers and licensing revenues, these benefits flow to only a few universities and from only a handful of patents.<sup>26</sup> Only a handful of schools have successfully translated research breakthroughs into blockbuster licensing revenue.<sup>27</sup> Most schools have achieved relatively pedestrian (though increasing) returns, an unsurprising result, considering most patents produce little revenue and do not lead to applied technology.<sup>28</sup>

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<sup>25</sup> See Mowery et al., *supra* note 5, at 104 (suggesting trend of increased university patent procurement began before Bayh-Dole).

<sup>26</sup> Eisenberg & Rai, *supra* note 12, at 292; see also Mowery et al., *supra* note 5, at 117 (surveying three universities and finding that small number of patents account for vast majority of licensing revenue).

<sup>27</sup> See *supra* notes 1-4 and accompanying text (discussing Florida State's success with Taxol).

<sup>28</sup> Simone A. Rose, *Patent "Monopolyphobia": A Means of Extinguishing the Fountainhead*, 49 CASE W. RES. L. REV. 509, 518 (1999) ("In reality, the majority of patents are not commercialized.").

Despite mediocre results for federally funded research, industry-funded projects could be the goose laying the golden eggs that universities seek. A number of writers, however, have questioned the propriety of close relationships between industry and academic institutions.<sup>29</sup> Improved ties between industry and academia endanger academic independence. Academic institutions may risk a kind of industry capture, compromising the educational mission.<sup>30</sup> Most importantly, strong ties to business—the provider of funds in such relationships—may erode academic integrity and create conflicts of interest. With closer ties to industry, researchers may import corporate values into the academic environment, displacing openness with secrecy. If these concerns are valid, then the CREATE Act may encourage an unpleasant trend.

With growing patent portfolios and industry interaction, universities will find themselves litigating patent suits more often. Unfortunately, *Madey* and *Integra* form heads and tails to the same unlucky penny for university researchers. As large areas of basic research are patented, academic researchers will suffer elevated exposure to liability, owing to *Madey*'s restriction of the experimental use exception. On the flip side, *Integra* allows the some researchers to enforce more easily their upstream biomedical research tool patents against infringers. Though seemingly a victory for researchers, *Integra* may hinder the progress of basic research, harming society and prompting questions about the propriety of allowing patents on upstream research.

### C. WHERE TO GO FROM HERE

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<sup>29</sup> See generally, e.g., Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 TEX. L. REV. 1363 (1988) (viewing traditional academic freedom in light of increased sponsored research).

<sup>30</sup> See *infra* notes 90-92 and accompanying text (discussing financial incentive to produce biased research results).

Part II of this paper describes the past twenty-five years of legislative and judicial changes in patent laws and policies affecting university research.<sup>31</sup> Part III discusses four dangers those changes pose to universities and society: (1) overestimation of patent licensing revenues; (2) thinning public domain for basic research; (3) loss of academic integrity; and (4) effects on society.<sup>32</sup> Part IV suggests two ways to create a more appropriate role for patent laws in university research and addresses potential concerns.<sup>33</sup> Part V concludes.

## II. CURRENT PATENT LAWS

### A. THE BAYH-DOLE ACT: PATENTING FEDERALLY FUNDED RESEARCH

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<sup>31</sup> See *infra* notes 34-73 and accompanying text.

<sup>32</sup> See *infra* notes 74-99 and accompanying text.

<sup>33</sup> See *infra* note 100 and accompanying text.

Prior to 1980, federal agencies that funded university research<sup>34</sup> generally retained patent rights in discoveries.<sup>35</sup> In theory, innovations obtained with public funds should redound to the public's benefit, justifying the agencies' retention of patent rights.<sup>36</sup> Patents often languished under federal ownership, however, where mismanagement and bureaucratized licensing schemes repelled potential industrial collaborators.<sup>37</sup>

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<sup>34</sup> Federal agencies also fund nonuniversity, nonprofit research. Although the Bayh-Dole Act applies to all federally funded research, the scope of this paper is limited to the university setting.

<sup>35</sup> Rubin et al., *supra* note 9, at 60-61; see also Mary Eberle, Comment, *March-in Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 158 (1999) ("Prior to the [Bayh-Dole] Act, the patent rights were retained by the federal funding agencies themselves." (citations omitted)).

<sup>36</sup> Rubin et al., *supra* note 9, at 60.

<sup>37</sup> *Id.* at 60-61; see also Newberg & Dunn, *supra* note 11, at 194 ("[F]irms had relatively little incentive to invest in developing technologies that could be licensed by any competitor."). *But see* Eisenberg, *supra* note 8, at 1702-05 (arguing statistics used to show government patent mismanagement were incomplete and biased).

Responding to lackluster commercialization of publicly funded research, Congress passed comprehensive technology transfer legislation in 1980.<sup>38</sup> The Bayh-Dole Act, a part of that legislation,<sup>39</sup> overhauled laws governing ownership of patents on federally funded research.<sup>40</sup> Citing numerous policy goals,<sup>41</sup> Congress changed patent ownership rules to allow universities to procure patent protection for technologies created with federal funds.<sup>42</sup> To ensure universities would transfer patented research to industry, Congress retained “march-in rights,” giving federal agencies a limited power to force universities to grant a nonexclusive license.<sup>43</sup>

For universities, the Bayh-Dole regime augured a new era for innovation.<sup>44</sup> A number of universities created technology transfer offices, designed to procure patent protection and to cash in on lucrative patent licenses.<sup>45</sup> By many accounts, the new

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<sup>38</sup> Eisenberg, *supra* note 8, at 1663-64. Congress’s power to form patent policy derives from the Intellectual Property Clause of the Constitution. U.S. CONST. art. I, § 8, cl. 8.

<sup>39</sup> Congress also passed the Stevenson-Wydler Technology Innovation Act, Pub. Law 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. § 3701-3714), which governs federal research labs.

<sup>40</sup> According to Professor Eisenberg, “[t]he year 1980 marked a sea change in U.S. government policy toward intellectual property rights in the results of government-sponsored research.” Eisenberg, *supra* note 8, at 1663.

<sup>41</sup> Congress codified seven goals for its new patent policy: (1) “to promote the utilization of inventions arising from federally supported research”; (2) “to encourage maximum participation of small business firms in federally supported research”; (3) “to promote collaboration between commercial concerns and . . . universities”; (4) to encourage use of inventions by nonprofit organizations “without unduly encumbering future research and discovery”; (5) “to promote the commercialization and public availability of inventions made in the United States”; (6) “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions”; and (7) to minimize administration costs. 35 U.S.C. § 200 (2000).

<sup>42</sup> Despite the altered stance on allowing university patent ownership, the Bayh-Dole Act does place a number of qualifications on university rights. See *generally id.* §§ 202-203.

<sup>43</sup> *Id.* § 203. For a discussion of march-in rights, see generally Eberle, *supra* note 35.

<sup>44</sup> Nearly 90% of university research funding comes from the federal government. Dueker, *supra* note 7, at 457 tbl. 2. Any change in patent policy for federal funding will therefore fundamentally alter the way universities approach patenting and licensing.

<sup>45</sup> The University of Georgia maintains its Technology Commercialization Office to “facilitates the transfer of technology developed at The University of Georgia to commercial enterprises where the technology can be put to beneficial use.” *Technology Commercialization*, at <http://www.ovpr.uga.edu/tco/> (last visited April 24, 2005).

system has been a huge success, increasing both patent procurement and licensing revenue at universities.<sup>46</sup>

## B. THE CREATE ACT

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<sup>46</sup> Mark L. Gordon, *University Controlled or Owned Technology: The State of Commercialization and Recommendations*, 30 J. COLLEGE & UNIV. L. 641, 642 (2004) (citing survey of universities reporting total of \$1.267 billion in licensing revenue).

As the federal government and universities have transformed their relationship over the past 25 years, private industry too has nestled up to university researchers. Although still a relatively small percentage of total university research funding, private industry contributions have grown significantly.<sup>47</sup> These relationships provide academic researchers with an alternative to federal funding, and industry receives the benefit of access to preeminent scientists and their graduate staffs.<sup>48</sup>

Just as more companies were recognizing the benefits of university research, the Federal Circuit tossed a monkey wrench into the university–industry alliance. In *OddzOn*, the court affirmed the trial court’s decision to consider research team members’ earlier confidential innovations as prior art, making the new invention unpatentable for obviousness.<sup>49</sup> At the time, statutory law only protected inventors from anticipatory prior art if they owned rights to that art.<sup>50</sup>

By passing the CREATE Act, Congress intervened to overcome the *OddzOn* roadblock to patentability.<sup>51</sup> The Act amended 35 U.S.C. § 103(c) to allow universities and industry to remove the prior art barrier by establishing a written joint research agreement before making an invention.<sup>52</sup> The Act reflects a more realistic view of scientific research, where team structure often requires the sharing of confidential information to achieve progress.<sup>53</sup> By easing patentability requirements for cross-

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<sup>47</sup> Newberg & Dunn, *supra* note 11, at 193.

<sup>48</sup> Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J. L. REFORM 141, 157 (2004).

<sup>49</sup> *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (1997)

<sup>50</sup> 35 U.S.C. § 103(c) (2000), *superseded by* 35 U.S.C.A. § 103(c) (West 2005).

<sup>51</sup> 150 Cong. Rec. H10219-02 (November 20, 2004) (statement of Rep. Sensenbrenner) (“[T]he bill responds to the 1997 [*OddzOn*] decision of the Federal Circuit Court of Appeals by clarifying that prior inventions of team members will not serve as an absolute bar to the patenting of the team’s new invention.”).

<sup>52</sup> 35 U.S.C.A. § 103(c)(3) (West 2005).

<sup>53</sup> Cf. Anna Martina Tyreus, Note, *H.R. 2391: Protecting Universities in Collaborative Research*, 82

organizational research teams, Congress has paved the way for greater university–industry collaboration.

C. *MADEY V. DUKE UNIVERSITY*: RESTRICTING THE EXPERIMENTAL USE EXCEPTION

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WASH. U. L.Q. 557, 576 (2004) (arguing that under original § 103(c), Congress wanted to encourage sharing knowledge between research team members working for the same employer).

The Federal Circuit upheld a “very narrow” experimental use defense to patent infringement in *Madey v. Duke University*.<sup>54</sup> Despite upholding the exception’s limited availability, the court demonstrated its practical futility for university researchers by denying Duke’s right to the defense.<sup>55</sup> Under the *Madey* rule alleged infringers may claim the experimental use exception only if their use of the patented invention “was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”<sup>56</sup>

As a nonprofit, education-oriented institution, Duke presented a sympathetic defendant had the Federal Circuit wished to implement a strong experimental use exception. The university’s actions enhanced its sympathetic status: University

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<sup>54</sup> 307 F.3d 1351, 1361 (2002). The experimental use exception has its roots in two opinions written by Justice Story in 1813. See *Whittemore v. Cutter*, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813) (“[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”); *Sawin v. Guild*, 21 Fed. Cas. 554, 555 (C.C.D. Mass. 1813) (stating action is infringement if “not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification”). Following the inception of the Federal Circuit, a steady flow of cases have narrowed the common-law doctrine. See generally, e.g., *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862-63 (1984), *superseded on other grounds by* 35 U.S.C. § 271(e) (2000) (denying experimental use exception to generic drug manufacturer seeking to generate test data for FDA approval prior to drug patent’s expiration); *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1348-49 (2000) (denying experimental use exception to testing of egg-injection machines).

<sup>55</sup> *Madey*, 307 F.3d at 1360.

<sup>56</sup> *Id.* at 1363.

resources paid the patentee's salary as a faculty member and built housing for the infringing devices.<sup>57</sup>

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<sup>57</sup> *Id.* at 1352.

After the patentee resigned from the university—following a ten-year relationship—the university continued to operate the patentee’s devices for noncommercial research.<sup>58</sup> The patentee objected and filed an infringement suit in the District Court for the Middle District of North Carolina. Focusing on Duke’s educational, nonprofit nature, the district court granted the university’s experimental use defense.<sup>59</sup>

The Federal Circuit reversed the district court’s experimental use ruling.<sup>60</sup> The court first said the alleged infringer bears the burden of proving the exception applies; the patentee need not prove an act is not experimental.<sup>61</sup> The court then chastised the district court for focusing on Duke’s nonprofit, educational status.<sup>62</sup> Moreover, the court

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<sup>58</sup> *Id.* at 1353. Though the patentee eventually resigned, he claimed Duke removed him as director of the lab for the purpose of taking possession of the patented devices. *Id.* at 1352-53.

<sup>59</sup> *Id.* at 1356. The district court looked beyond Federal Circuit precedent, citing a 1935 district court ruling as support for its experimental use ruling. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420, 427 (M.D.N.C. 2001) (citing *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936)). The Federal Circuit in *Madey*, however, emphasized *Ruth*’s nonbinding status and rejected its analysis. *Madey*, 307 F.3d at 1362. Without *Ruth* as support, the district court’s ruling could not stand against the weight of Federal Circuit precedent. *Id.*

<sup>60</sup> *Madey*, 307 F.3d at 1352.

<sup>61</sup> *Id.* at 1361.

<sup>62</sup> *Id.* at 1362.

explicitly excluded ordinary university research from the exception, arguing that even research without commercial application furthers a university's business objectives, such as education.<sup>63</sup> *Madey* effectively forbids universities from evading infringement liability under the experimental use exception.

D. *INTEGRA LIFESCIENCES I, LTD. V. MERCK KGAA*: EXPANDING THE POWER OF RESEARCH TOOL PATENTEES

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<sup>63</sup> *Id.* The court stated:

[M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

*Id.*

Congress added the 35 U.S.C. § 271(e)(1) safe harbor in 1984 to protect drug manufacturers seeking FDA approval for a generic version of a patented drug already on the market.<sup>64</sup> The statute's language is broad, however, potentially protecting all drug manufacturers: "It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . ."<sup>65</sup> In *Integra*, the Federal Circuit had an opportunity to determine the limits of the safe harbor.<sup>66</sup>

When Scripps researchers conducted investigatory anti-angiogenesis research in the 1990s, they used a peptide sequence patented by Integra.<sup>67</sup> Integra and Merck,

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<sup>64</sup> The statute, like the CREATE Act, directly responded to a Federal Circuit decision. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862-63 (1984), *superseded on other grounds by* 35 U.S.C. § 271(e) (2000) (denying common-law exception to generic drug manufacturer seeking to generate test data for FDA approval prior to drug patent's expiration).

<sup>65</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>66</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *cert. granted sub nom. Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 823 (2005). The Supreme Court heard oral arguments April 20, 2005 regarding Merck's appeal, and news reports suggested the Court favored a broader Section 271(e)(1) construction. Susan Decker & Greg Stohr, *Justices Question Decision Limiting Drug Research*, Record (Bergen County, N.J.), Apr. 21, 2005, at B4 (noting Justice O'Connor's comments).

<sup>67</sup> *Id.* at 862. Angiogenesis refers to the creation of new blood vessels; inhibiting angiogenesis could have a number of health benefits, including slowing tumor growth. *Id.* at 863.

who funded Scripps's research, tried to negotiate a license but failed.<sup>68</sup> Integra sued Merck, Scripps, and the researcher who used the peptide sequence.<sup>69</sup>

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<sup>68</sup> *Id.*

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

Merck claimed the 271(e)(1) safe harbor protects any drug maker seeking FDA approval, even for investigatory research.<sup>70</sup> The Federal Circuit, however, confined the safe harbor to late-stage drug development and FDA clinical testing. Using strong language, the court nearly limited the provision's protection to generic drug makers seeking "FDA approval of a patented pioneer drug already on the market."<sup>71</sup> The Federal Circuit further expressed strong concern that protecting early-stage drug investigation would "vitiating the exclusive rights of patentees owning biotechnology tool patents."<sup>72</sup> Expanded protection for research tool patents may be seen as a great victory for universities, who often patent research tools in the course of conducting basic research.<sup>73</sup>

### III. DANGERS OF THE CURRENT SYSTEM

#### A. OVERESTIMATION OF ECONOMIC BENEFITS TO UNIVERSITIES

Supporters often overstate the patenting success of universities. Though total university patents have increased, only a handful of academic institutions account for the vast majority of university-owned patents; most institutions own few patents.<sup>74</sup> Accordingly, the bulk of university licensing revenue goes to a few institutions.<sup>75</sup> Even large patent portfolios are no guarantee of licensing success: Most patents fail to

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<sup>70</sup> See *id.* at 865-66 (framing issue as "whether the . . . safe harbor reaches back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval"). Merck had some authority for its claim, including a district court decision including preliminary research under the safe harbor. See *generally* *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 U.S. Dist. LEXIS 19361 (S.D.N.Y. 2001) (ruling in favor of pioneer drug maker).

<sup>71</sup> *Integra*, 331 F.3d at 867.

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

<sup>73</sup> After making breakthroughs in basic science, many biotech researchers patent "research tools," including biological and chemical structures used to conduct basic research.

<sup>74</sup> See *supra* note 26 and accompanying text.

<sup>75</sup> Dueker, *supra* note 7, at 466-67 (stating that licensing usually only provides about 1-2% of a university's research budget). Joyce Brinton, director of Harvard University's technology transfer program, believes licensing will rarely ever provide more than 5% of a university's research budget. *Id.* at 453.

produce substantial revenue over their lifetimes, and many produce no revenue at all.<sup>76</sup>

In fact, at some universities administrative costs of a patent portfolio (for example, patent filing fees) outpace licensing revenue, causing a net loss.<sup>77</sup>

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<sup>76</sup> Rose, *supra* note 28, at 518.

<sup>77</sup> Tamsen Valoir, *Government Funded Inventions: The Bayh-Dole Act and the Hopkins v. CellPro March-in Rights Controversy*, 8 TEX. INTELL. PROP. L.J. 211, 235-36 (2000).

Overestimation of licensing benefits leads to overconfidence in university technology transfer offices. Industry partners interested in licensing university patents often find the asking price unacceptable.<sup>78</sup> Universities earn very little licensing revenue from patents on early research because businesses are unwilling to take significant risks on unproven technologies. Potential industry licensees often shy away from licensing early research because of the uncertainty of avenues for development.<sup>79</sup>

#### B. UPSTREAM BLOCKAGE: AN UNINTENDED CONSEQUENCE OF WIDESPREAD UNIVERSITY PATENT OWNERSHIP

Although the success of Bayh-Dole has been overstated, the fact remains that universities are acquiring patents in greater numbers.<sup>80</sup> Unfortunately, most of those patents cover basic research results and research tools, both of which are necessary for later downstream research.<sup>81</sup> Rampant upstream patenting of basic research by universities may impede other nonprofit and educational institutions from conducting

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<sup>78</sup> See generally Alan Cohen, *Companies Want to License Academic Research, but Universities Don't Always Make It Easy*, 4 INTELL, PROP. L. & BUS. 50 (Dec. 2004) (discussing high fees requested by university licensors).

<sup>79</sup> Dueker, *supra* note 7, at 466-67.

<sup>80</sup> See *supra* note 12 and accompanying text.

<sup>81</sup> Eisenberg & Rai, *supra* note 12, at 292.

important research.<sup>82</sup> The resulting over-privatization of early research creates gridlock, a “tragedy of the anticommons.”<sup>83</sup>

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<sup>82</sup> See Eisenberg, *supra* note 8, at 1667 (arguing upstream patenting “threatens to impoverish the public domain of research science”).

<sup>83</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698, 698 (1998). Professor Heller more fully explained the concept of “tragedy of the anticommons” in a previous article. See Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 *HARV. L. REV.* 621, 668 (1998) (defining anticommons as “a property regime in which multiple owners hold effective rights of exclusion in a scarce resource”).

Researchers at academic institutions may be discouraged from conducting certain research for fear of running afoul of another institution's patent rights.<sup>84</sup> Under the rule in *Madey*, even ordinary, noncommercial university research may incur

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<sup>84</sup> Robert Kneller, *University-Industry Cooperation and Technology Transfer in Japan Compared with the United States: Another Reason for Japan's Economic Malaise?*, 24 U. PA. J. INT'L ECON. L. 329, 342 (2003) ("[T]he explosion of IP claims to early-stage discoveries whose usefulness is often limited to research (i.e., "research tools") may dissuade some university laboratories or companies from pursuing research in a particular area, either because they are afraid of infringement suits or because they believe that the transaction costs of negotiating licenses with numerous IP owners would be too costly.").

significant threat of liability.<sup>85</sup> The narrowed experimental use exception provides no protection for university researchers who work with basic research tools.<sup>86</sup> Likewise, after *Integra*, university researchers may not claim the statutory safe harbor either, unless working for a generic drug manufacturer during FDA trials.

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<sup>85</sup> But see Cristina Weschler, Note, *The Informal Experimental Use Exception: University Research After Madey v. Duke University*, 79 NYU L. REV. 1536, 1536 (2004) (arguing that informal experimental use exception in academic community may provide enough protection even without robust common-law exception). *Madey* was not necessarily wrongly decided; in fact, the Federal Circuit showed appropriate circumspection by curtailing a judicially created rule in an area of law thoroughly covered by statute. Nevertheless, the current statutory scheme effectively encourages universities to procure monopoly rights to basic science and to adopt restrictive policies on sharing results (a result of close ties to industry). Until *Madey*, the experimental use exception provided noncommercial academic researchers with at least some protection when wading through the monopoly minefield. After *Madey*, though, researchers are completely exposed to infringement suits should other universities enforce their upstream patents.

<sup>86</sup> See Mueller, *supra* note 21, at 3 (giving example of company suing forty universities and two hundred academic researchers).

To avoid liability, academic researchers may be forced to purchase a license from the patentee, increasing research costs and leading to gridlock-inducing royalty stacking.<sup>87</sup> In a sense, patent royalties impose a tax on downstream product development.<sup>88</sup> For universities with small research budgets and little licensing revenue, the costs of purchasing patent licenses could halt research projects. Those universities may then turn to industry, who either own their own upstream patents or have the bankroll to license; prolonged reliance on industry could produce a loss of academic freedom, as discussed in the next section.

### C. LOSS OF ACADEMIC INTEGRITY

Closer ties between universities and industry, though clearly a goal of Congress under the Bayh-Dole and CREATE Acts, may not truly serve universities' interests. Universities now have a "revenue motive to pursue patent rights."<sup>89</sup> Indeed, universities measure the success of their patent portfolios by the amount of licensing revenue obtained, not by the number of applied technologies created. Yet rather than produce blockbuster licenses for the universities, the collaborations have resulted in biased research results and adoption of industry's "secrecy" culture by academic researchers.

Industry funding often casts a pall over academic research, tainting it with conflicts of interests or at least the appearance of impropriety.<sup>90</sup> Indeed, research shows a statistically significant bias in the results of academic research funded by

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<sup>87</sup> Kneller, *supra* note 84, at 343 ("[T]he price of the final product may be burdensome for end users because high royalties have to be paid to use the many patented technologies incorporated in the final product (i.e., 'royalty stacking').").

<sup>88</sup> Eisenberg, *supra* note 8, at 1714; Eisenberg & Rai, *supra* note 12, at 300.

<sup>89</sup> Eisenberg, *supra* note 8, at 1722.

<sup>90</sup> As Professor Eisenberg notes, industry funding creates an incentive for researchers to reach conclusions agreeable to the sponsor. Eisenberg, *supra* note 29, at 1375.

industry, favoring the position championed by the sponsor.<sup>91</sup> Other researchers who reach results unfavorable to their sponsor may choose not to publish, rather than give in to bias.<sup>92</sup>

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<sup>91</sup> Michael J. Malinowski, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 WID. L. SYMP. J. 47, 59-60 (2001); Valoir, *supra* note 77, at 236. The bias need not be conscious to pose a problem. In fact, subconscious bias may cause a larger problem because even conscientious researchers may not know their own tendencies and thus will not be able to guard against them.

<sup>92</sup> Eisenberg, *supra* note 29, at 1376. Granted, hiding unfavorable results constitutes a bias of its own.

Researchers who rely on industry funding may adapt to industry culture as well, abandoning the openness of science for the secrecy of business.<sup>93</sup> Businesses that fund industry research “often seek to restrict the dissemination of research results.”<sup>94</sup> Professor Eisenberg cites two problems that result from academic secrecy: (1) conflict with universities’ “traditional role of expanding the storehouse of publicly held knowledge” and (2) isolation of industry-funded researchers from the academic community.<sup>95</sup>

With a loss of academic integrity comes internal discord as well. Universities and researchers both want patent rights; inevitably, disputes arise between employer and employee.<sup>96</sup> Litigation of that nature merely adds to patent portfolio administration costs and subtracts from institutional goodwill.

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<sup>93</sup> Not all writers agree that industry values threaten academic culture. See Newberg & Dunn, *supra* note 11, at 212-18 (listing reasons commercial and academic cultures can coexist). Newberg and Dunn write that secrecy exists in many areas of academic research, independent of industry influence. *Id.* at 213-14. Their examples, however, fail to make the point. For example, the academic practice of hiding the names of research *subjects* in order to protect personal privacy hardly equates to industry’s practice of hiding research *results* from the broader scientific community.

<sup>94</sup> Eisenberg, *supra* note 29, at 1375.

<sup>95</sup> *Id.* Professor Eisenberg also discusses the danger to “the academic research agenda” presented “by industry and by mission-oriented government agencies.” *Id.* at 1376-77. Though relevant and important, the issue—whether science progresses better when guided by a particular goal or when pursued without practical purpose—far exceeds the bounds of this paper.

<sup>96</sup> See *generally* Bd. of Educ. v. Am. Bioscience, Inc., 333 F.3d 1330 (2003) (concerning dispute between university and former research assistant), *Madey v. Duke Univ.*, 307 F.3d 1351 (2002)

#### D. SOCIETAL INTEREST IN ROBUST ACADEMIC RESEARCH AND APPLIED TECHNOLOGY

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(concerning dispute between university and former faculty member).

Society has a vested interest in promoting scientific and technological advancement. Perhaps foremost is society's interest in advanced pharmaceuticals, including cancer treatments<sup>97</sup> and gene therapy. The Federal Circuit's ruling in *Integra* and the Bayh-Dole Act together impose substantial obstacles to rapid development of these drugs. The Bayh-Dole Act has allowed universities to own large numbers of research tool patents, and the Federal Circuit denied pioneer drug makers safe harbor from those patents. Drug manufacturers must either seek licenses or shift operations overseas, costing domestic jobs and delaying scientific progress.<sup>98</sup>

Although Bayh-Dole may have stimulated patenting activities at universities (though even that point is disputable), the Act "does not presume that patents are necessary to motivate grantees to perform research with federal funds, but rather that patents will promote subsequent utilization and development of inventions arising from federally supported research."<sup>99</sup> In other words, the volume of research itself has never been the problem; rather, the commercialization of applied research has been deficient. That deficiency remains, and Congress and the Federal Circuit have placed more roadblocks—upstream patent rights—in the way of successful development of applied technologies.

#### IV. PROPOSALS FOR A HEALTHIER RELATIONSHIP BETWEEN PATENT LAW AND UNIVERSITY RESEARCH

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<sup>97</sup> The angiogenesis research at the heart of *Integra* had substantial potential to kill cancer tumors. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 (Fed. Cir. 2003), *cert. granted sub nom. Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 823 (2005).

<sup>98</sup> Alison Ladd, Note, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 354-55 (2005) (discussing potential loss of pharmaceutical companies to foreign countries).

<sup>99</sup> Eisenberg & Rai, *supra* note 12, at 300.

First, innovations supported by federal funding should pass into the public domain. The federal government showed its poor management skills by not farming its patents out to industry. University technology transfer offices have not fared much better, instead patenting mostly upstream, basic research. A balkanized system of fundamental research simply does not serve the public interest.

Passing inventions into the public domain would satisfy Congress's goal of benefiting the public, whose tax money funds the research. A robust public domain would also allow university researchers to pursue freely their research. Scientists could no longer patent large chunks of basic research and hold future inventions hostage to upstream licenses and royalty stacking. Neither would researchers be beholden to fear of infringement liability.

Second, Congress should pass a statutory experimental use exception. Pertaining only to federally funded research, the statutory exception would allow universities to conduct most basic research without fear of liability. By passing their new discoveries into the public domain, university researchers would pose few dangers to existing patentees.

Third, the Supreme Court should rein in the Federal Circuit by reversing the *Integra* decision. The Federal Circuit's constrained reading will subject innovative drug manufacturers to unacceptably high royalty and licensing fees, which will have two detrimental effects. First, drug manufacturers will pursue new drugs more cautiously, delaying their market debut. Second, after successfully producing a drug, the manufacturer will pass on the higher research costs to the public.

Supporters of the current system will point to the economic success of the past twenty-five years, claiming the system is not broken and thus need not be fixed. *Madey*

and *Integra*, however, are the first warning signs that the system has broken.<sup>100</sup> As upstream research patents multiply, downstream researchers either get saddled with stacked royalties or get discouraged from performing research altogether.

Critics may also contend that these ideas will cost universities much-needed licensing revenue. Even assuming the critics' statistics are correct, however, overconfidence in licensing revenues will only cause increased corporatization of universities. Rather than seeking to transition science into applied technologies, universities currently seek a maximum revenue stream, an approach that limits available industry partners. Meanwhile, industry partners who will pay the high fees will also insist on confidentiality, antithetical to usual scientific values. In reality, though, blockbuster university patents are few and far between, meaning universities will be missing something they never even had.

## V. CONCLUSION

Academic institutions must collectively ask whether current patent policies offer more benefits than costs for university research. Although universities seem to receive manifold benefits from current laws, supporters of the current system have overstated the case. For every university with a Taxol-like windfall, there are a hundred other universities just breaking even.

In addition, the public may question the propriety of using federal funds to secure monopoly rights in research (essentially using public tax money to create conditions allowing a private tax). Widespread upstream patenting freezes basic researchers with fear of liability and prices downstream researchers out of the market. Moreover the

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<sup>100</sup> Some suggest spiraling tuition costs are directly attributable to the Bayh-Dole Act, another sign of a broken system. Mark R. Wisner, *Recent Development: Proposed Changes to the Laws Governing Ownership of Inventions Made with Federal Funding*, 2 TEX. INTELL. PROP. L.J. 193, 196 (1994) (citing E. Negin, *Education: Why College Tuitions Are So High*, 271 ATLANTIC 32 (Mar. 1993)).

monopoly mentality, fed by closer industry ties, threatens what remains of “open science.” Collectively, the government, academia, and the public must reinvigorate the public domain to protect scientific researchers and benefit technology consumers.