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# The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?

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# THE EXPERIMENTAL USE EXCEPTION TO PATENT INFRINGEMENT: DO UNIVERSITIES DESERVE SPECIAL TREATMENT?

Elizabeth A. Rowe

- I. INTRODUCTION
  - A. The Outcry from Madey
  - B. A Narrow Experimental Use Exception Makes Sense
  - C. The New Face of University Research
  - D. The Tradeoff Between Patent Protection and Incentives to Innovate
  - E. The Reality of the Marketplace
- II. BACKGROUND ON THE EXCEPTION
  - A. Profit or Financial Gain
  - B. Furthering Business Interests
    - 1. Experimental Use and the Pharmaceutical Industry
    - 2. Madey v. Duke University: Laying Down the Law for Universities
  - C. The Hatch-Waxman Act: Legislature Overturns Roche
    - 1. Description of the Hatch-Waxman Act
    - 2. The Supreme Court Interprets the Hatch-Waxman Act
- III. THE BAYH-DOLE ACT AND THE COMMERCIALIZATION OF ACADEMIC RESEARCH
  - A. Changes in Attitude About University Discoveries
  - B. Universities Profit from Patent Licenses
  - C. Universities Enforce their Patent Rights
  - D. Relationships with Industry
- IV. THE PRACTICAL REALITY: RESEARCH WILL LIVE ON
  - A. The Effect of Merck v. Integra
  - B. Licensing: Just Ask Nicely
  - C. Tolerating Universities' Patent Infringement
    - 1. The Honor System
    - 2. Difficulties of Litigation
    - 3. University Relationships Are Important
    - 4. Sovereign Immunity for State Universities
- V. THE EXEMPTION IS APPROPRIATELY NARROW
  - A. Patenting Promotes Innovation and the Public Good
  - B. The Case for Expansion Is Not Persuasive
  - C. The Scope of Proposals for Expansion Is Hard to Define
  - D. Congress Should Expand the Exemption Only for Compelling Reasons
    - 1. Exemptions to Date
    - 2. A Proposed Standard
- VI. CONCLUSION

## THE EXPERIMENTAL USE EXCEPTION TO PATENT INFRINGEMENT: DO UNIVERSITIES DESERVE SPECIAL TREATMENT?

Elizabeth A. Rowe\*

#### I. INTRODUCTION

Inventor Ivan owns a patent on a new Gizmo. He has spent a substantial portion of his time and resources to develop the Gizmo. He has also spent thousands of dollars on his patent attorneys to obtain the patent. Ivan had to wait over two years for the patent application to be processed and approved. But it was all worth it. Our patent laws grant Ivan a negative right—the right to exclude others from practicing his invention during the period of the patent.<sup>1</sup>

The local university is using Ivan's invention to further its own research. The university's research will allow the university to train many graduate students and could potentially result in large profits for the university. The university did not seek Ivan's permission to use the Gizmo. Should the university be liable to Ivan for patent infringement? Whether Ivan can prevail depends on whether the university can claim its unauthorized use of the Gizmo is permitted under the experimental use exception. The experimental use exception<sup>2</sup> is a common law exception to the patent-holder's exclusive right of use.<sup>3</sup> It permits the use of another's patented device when such use is for philosophical inquiry, curiosity, or amusement.<sup>4</sup> Judging from the scholarship on this topic to date, most commentators would probably answer the question posed by

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<sup>1.</sup> See 35 U.S.C. § 154 (2000) (granting patent rights for twenty years from the filing date of the patent application); see also id. § 271 (2000). "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." *Id.* § 271(a).

<sup>2.</sup> There is another experimental use defense in patent law, also known as the public use defense, that forbids an inventor from obtaining a patent on an invention if the invention was in public use or on sale (rather than being used for experimental purposes by the inventor) for more than a year prior to the date of the patent application. Id. § 102(b). It covers experimentation conducted by the inventor himself on the invention. This Article does not address that defense. Rather, it examines the common law experimental use exception where the courts determine other people's alleged experimental use of the patentee's invention.

<sup>3.</sup> Experimental use is considered both an exception and a defense to patent infringement. See Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 19-21 (2001).

<sup>4.</sup> See, e.g., Embrex Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1351 (Fed. Cir. 2000); see also infra Part II.

the hypothetical in the negative: the university should not be liable to Ivan for patent infringement. This Article, however, rejects such an answer and asserts that the university should be liable.

#### A. The Outcry from Madey

The experimental use exception has recently come under attack by many who consider it too narrow.<sup>5</sup> They fear that the courts' "narrowing" of the experimental use exception will stifle research and innovation.<sup>6</sup> Much of the discontent with the doctrine has been spurred by a relatively recent Federal Circuit opinion, *Madey v. Duke University*, which makes clear that a research university does not receive immunity under the experimental use exception when its researchers engage in research or conduct experiments using patented inventions.<sup>7</sup> This ruling has created an outcry because over the years universities appear to have assumed, albeit incorrectly, that their research was protected under the doctrine and thus that their scientists need not seek permission from patent owners before using patented devices.<sup>8</sup>

Virtually all commentators since *Madey* have criticized the ruling and its effect on the experimental use exception.<sup>9</sup> For instance, one commentator calls it "a seemingly disingenuous opinion that neither conforms to the implications of precedent nor explains the reasons for steering the law in a different direction, but pretends that prior courts never meant to give research science special treatment."<sup>10</sup> Similarly, another commentator asserts that the *Madey* court "stretched the concept of commercial use" and that the current experimental use exception "bears little relation to the implications of a particular experimental use for the public benefits of follow-on innovation."<sup>11</sup>

#### B. A Narrow Experimental Use Exception Makes Sense

This Article enters the discussion to offer a different and opposing viewpoint. It takes the position that a narrow experimental use exception is consistent with existing law, consistent with sound public policy, and appropriate for the current nature of university research. Contrary to the picture painted by critics of a rapid "narrowing" of the exception by the courts, in reality, the experimental use exception has always been very narrow. To the extent that universities or others have taken liberties with a broader interpretation of the doctrine, the holding in *Madey* serves simply as a wake-up call clarifying the status of the law. Having moved from a philosophical

<sup>5.</sup> See, e.g., Andrew J. Caruso, Comment, The Experimental Use Exception: An Experimentalist's View, 14 ALB. L.J. SCI. & TECH. 215, 220 (2003); Natalie M. Derzko, In Search of a Compromised Solution to the Problem Arising From Patenting Biomedical Research Tools, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347, 365-66 (2004); Katherine J. Strandburg, What Does The Public Get?: Experimental Use and the Patent Bargain, 2004 WIS. L. REV. 81 (2004); Kevin Sandstrom, Note, How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences Ltd. v. Merck, 30 WM. MITCHELL L. REV. 1059, 1067 (2004).

<sup>6.</sup> See, e.g., id.

<sup>7.</sup> Madey v. Duke Univ., 307 F.3d 1351, 1361-63 (Fed. Cir. 2002); see infra Part II.B.2.

<sup>8.</sup> See Rebecca S. Eisenberg, Patent Swords and Shields, 299 SCIENCE 1018, 1019 (2003).

<sup>9.</sup> See supra note 5.

<sup>10.</sup> Eisenberg, supra note 8, at 1019.

<sup>11.</sup> Strandburg, supra note 5, at 138-46.

experimentation model closer to a business for-profit model in research, it is important to consider the fairness of treating universities' patent infringement differently from that of their industry counterparts.

#### C. The New Face of University Research

The proper role for the experimental use exception at research universities is a complex issue with no easy answer. The main reason for the complexity lies in the changed nature of university research during the last two decades. University research used to be more akin to research for the sake of research, with university researchers engaged in their academic pursuits, anxious to publish their discoveries. Today the landscape has changed. University research has become more of a business, and indeed is sometimes difficult to distinguish from industrial research. Patenting, commercial development, high tech incubators, and partnerships with industry have become commonplace activities for universities.

The legal problem posed by the experimental use exception cannot be divorced from this context. To the extent *Madey* is viewed as posing a problem for university research, any consideration of a solution must be mindful of this shift in the nature of university research. It is not the old image of university research that should govern, but today's reality. Admittedly, this poses some tensions because it may be challenging to reconcile the purely academic norms and interests of university research with the profit-oriented, businesslike activity it is today. The former may deserve a broader experimental use exception, and perhaps that is why most critics of the doctrine, impliedly viewing university research from the "old" lens, disagree with *Madey*. However, this Article posits that the better approach entails reviewing the situation through the newer lens in determining the appropriate rule for patent infringement in university research.

A noteworthy irony underlies this issue: universities probably have much more to gain from the strict and narrow interpretation of the patent laws espoused in this Article than from the alternative (yet more vocal) viewpoint. That is because universities as a group are large patent-holders in this country.<sup>12</sup> They gain billions of dollars in revenues annually from patent licenses and royalties.<sup>13</sup> Any interpretation of the experimental use exception, or the patent laws generally, that would in effect permit greater erosion of patent-holders' rights would impose greater financial detriment to universities than the narrow interpretation under *Madey*.

#### D. The Tradeoff Between Patent Protection and Incentives to Innovate

The overarching theoretical question here concerns the tradeoff between protecting patentees' rights and maintaining incentives to innovate. It is of course difficult to determine the optimal level of patent protection for increasing invention and innovation. In the context of the experimental use exception, this Article posits that a narrow experimental use exception will have a more positive effect on incentives to innovate than will a broader exception. A narrow experimental use exception, the

<sup>12.</sup> See infra text accompanying note 115.

<sup>13.</sup> See infra Part IV.B.

status quo, strengthens incentives to invent and innovate, while a broad experimental use exception would provide disincentives to invest in patenting and innovation. This is especially so given the nature of modern university research and existing patent licensing practices.

#### E. The Reality of the Marketplace

Contrary to virtually all those who have written about the experimental use exception since *Madey*, I do not see the *Madey* opinion as the death knell of all research and innovation. A closer look at the practical reality reveals that several considerations inherent in the business of university research are likely to have a more powerful effect on the enforcement of the experimental use exception among researchers than the *Madey* decision. These considerations provide a kind of self-regulation that will continue to foster research and innovation.

Moreover, this Article examines two other considerations, not previously considered in combination by other commentators, which in effect already expand the experimental use exception, affording greater protection to universities where applicable. First, a recent United States Supreme Court opinion, *Merck KGaA v. Integra Lifesciences I, Ltd.*,<sup>14</sup> broadly interpreted a federal statute, permitting experimentation on patented drugs prior to expiration of their patents.<sup>15</sup> Thus, university research involving development of new drugs benefits from this ruling. Second, state universities enjoy sovereign immunity from patent infringement suits for damages, giving them far greater protection than any experimental use exception could provide.<sup>16</sup>

These gaps weigh in favor of saving and safeguarding the doctrine, rather than leaving it as an empty shell. The experimental use exception is still of consequence to private universities, individual researchers at state universities, industrial researchers, and the world of non-drug development researchers. Because each chip off the doctrine signals a further erosion of patent-holders' rights and an accompanying harm to the incentives to invent and innovate, careful consideration of the doctrine is still required.

In order to make the exclusive rights granted to a patent owner truly meaningful, not only must the infringement laws be strictly observed, but exceptions must remain narrow as well. To do otherwise would threaten to erode those rights. Not only is broadening the exception a step on a slippery slope, but any such broadening can also be very difficult to identify and manage, and can threaten to swallow the exception.

In some circumstances, however, strict adherence to the experimental use exception may stifle experimentation. As a result, any broadening of the exception should be defined by Congress in specific situations where a sufficiently compelling case has been made that the exclusivity granted to a patent owner will have an injurious effect on the public good and on innovation. Thus, under these circumstances, society's interests should trump the inventor's patent rights.

Part II of this Article provides background on the experimental use exception. Part III discusses the Bayh-Dole Act, its alteration of the landscape of university research,

<sup>14. 545</sup> U.S. 193 (2005).

<sup>15.</sup> Id. at 208; see infra Part II.C.2.

<sup>16.</sup> See infra Part IV.C.4.

and its impact on university patenting activity. Part IV explains why, in reality, university research will survive a narrow experimental use exception. Finally, Part V discusses why the experimental use exception is appropriately narrow and proposes a test that ought to guide Congress in deciding when legislative broadening is necessary.

#### II. BACKGROUND ON THE EXCEPTION

The experimental use exception is a judicially created doctrine that limits a patentholder's exclusive rights.<sup>17</sup> The highlights of its evolution and its current status in the case law (and legislatively) are described below.<sup>18</sup> It is important to realize that the exception was intended to be narrow from the beginning. In *Whittemore v. Cutter*,<sup>19</sup> the first case to apply the exception, Justice Joseph Story, ruling for the defendant, declared in dicta that the patent laws did not intend to punish a person who infringes a patent "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."<sup>20</sup> Accordingly, given the broad prohibition against any use of a patented invention without permission, the task entailed carving out a sliver of use that would not invade the patent-holder's exclusive rights. For Justice Story, this sliver included use for purely philosophical inquiry and use for determining whether the patented device works as it proclaims.

Further testimony to the exception's narrowness is the rare success of the defense.<sup>21</sup> It appears that over time, the focus of the inquiry shifted from whether the alleged infringing use was for profit or financial gain to whether it furthered one's legitimate business interests (regardless of profit). However, the courts never wavered from their extremely narrow interpretation of the doctrine. When that narrow interpretation was judicially applied to the pharmaceutical industry, Congress stepped in to provide the industry with special relief.<sup>22</sup> The Supreme Court's interpretation of that congressional act may now have the effect of expanding the common law experimental use exception in certain circumstances.

<sup>17.</sup> See Mueller, supra note 3, at 19.

<sup>18.</sup> For a listing of more of the older cases on the doctrine, see generally 5-16 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03 (2004).

<sup>19. 29</sup> F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>20.</sup> Id. at 1121.

<sup>21.</sup> Indeed, a review of cases reveals that the defense has defeated a patent infringement claim in only four instances and without much discussion from the courts on the reasons for such defeat. *See* Chesterfield v. United States, 159 F. Supp. 371, 376 (Ct. Cl. 1958) (finding the experimental use exception applicable when alloy was used only for testing and for experimental purposes); Dugan v. Lear Avia, 55 F. Supp. 223, 229 (S.D.N.Y. 1944) (holding one device non-infringing under the experimental use exception because it was not manufactured for sale); Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305, 333 (N.D. W. Va. 1937) (finding experimental use exception applicable when testing was done before going into commercial production); Finney v. United States, 188 U.S.P.Q. (BNA) 33, 35 (Ct. Cl. Trial Div. 1975) (finding the experimental use exception applicable where NASA used patented glove once during training experiment). The low number of successful cases utilizing the defense may also be attributable to patentees simply choosing not to sue those infringers whose activities are truly experimental within the narrow boundaries provided by the courts. As this Article suggests, there is a self-regulating mechanism in place that guides enforcement of the experimental use exception. *See infra* Part IV.

<sup>22.</sup> See infra text accompanying notes 75-76.

#### A. Profit or Financial Gain

The earliest cases creating the experimental use exception arose in the commercial context, involving businesses. It would not be until a century later that a case involving an academic institution, albeit indirectly, would arise,<sup>23</sup> and then another sixty-five years would pass before *Madey v. Duke University*<sup>24</sup> would specifically address academic institutions. This trend is notable in the context of the arguments made here because it demonstrates how rarely universities have confronted a legal battle on this issue. The timing also seems significant insofar as the most recent ruling arrived after the courts shifted the focus of their analysis from a profit or financial gain inquiry to a broader furtherance of ongoing business interests determination. Accordingly, even knowing nothing else about the case law, one would have expected (perhaps more easily in hindsight) the *Madey* court to rule as it did.

Originally, the courts focused on whether the alleged infringer intended to profit from the use of another's patent. If he did, the experimental use exception did not apply. Ever present throughout these early discussions was consideration of the effect on the patentee's exclusive rights. In *Sawin v. Guild*,<sup>25</sup> Justice Story again applied the experimental use exception to exempt alleged patent infringers who had no profit motive.<sup>26</sup> Finding for the defendant, he concluded that those who use the patented invention "for mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification" describing the invention, would not be held liable for patent infringement.<sup>27</sup> Drawing the line at the intent to profit made sense to this court because only those who infringe patents with the intent to profit financially actually deprive the patent owner of his "lawful rewards" preserved by the patent.<sup>28</sup> Accordingly, this case established the profit motive as the key determinant of whether the experimental use exception would exempt the alleged infringing activity.<sup>29</sup>

About fifty years later, in 1861, another court set out the current test for experimental use in *Poppenhusen v. Falke.*<sup>30</sup> The court clarified that courts had accepted the experimental use defense when the alleged infringing activity was "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement."<sup>31</sup> This test formed the current "truly narrow" experimental use exception, immunizing only those patent infringers seeking amusement or verifying that the invention worked as it should—not those motivated by financial gain.

In 1935, with *Ruth v. Stearns-Roger Manufacturing Co.*,<sup>32</sup> the first case involving the experimental use exception in the academic research context was decided. However, the defendant in *Ruth* was not an academic institution; rather, the defendant company illegally sold parts for a patented flotation device to several customers,

<sup>23.</sup> See infra text accompanying notes 32-36.

<sup>24. 307</sup> F.3d 1351, 1361-63 (Fed. Cir. 2002).

<sup>25. 21</sup> F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

<sup>26.</sup> Id. at 555.

<sup>27.</sup> Id.

<sup>28.</sup> Id.

<sup>29.</sup> Mueller, supra note 3, at 20.

<sup>30. 19</sup> F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

<sup>31.</sup> *Id*.

<sup>32. 13</sup> F. Supp. 697, 703 (D. Colo. 1935), rev'd on other grounds, 87 F.2d 35 (10th Cir. 1936).

including the Colorado School of Mines.<sup>33</sup> Customers who purchased these parts were able to use the improved device instead of purchasing a new instrument.<sup>34</sup> Although finding the defendant liable for contributory patent infringement, the district court exempted the sales to the Colorado School of Mines because the school used its instruments in conducting research.<sup>35</sup>

Consistent with its financial gain analysis, the court reasoned that because the school derived no financial benefit from the use of the patented device, its infringing research activities fell within the experimental use exception.<sup>36</sup> Academic institutions have interpreted this decision as providing them with broad protection from patent infringement when they engage in research. Indeed, most academic institutions freely infringed patents until 2002, when the Federal Circuit clarified the scope of the exemption in *Madey*.<sup>37</sup>

#### **B.** Furthering Business Interests

#### 1. Experimental Use and the Pharmaceutical Industry

The experimental use analysis soon shifted, considering not just the alleged infringer's profit motive but also whether the use occurred in the course of business. Accompanying this shift was the recognition that any use (not just profitable use) of the patentee's exclusive rights was harmful and in violation of patent laws. That rationale is clear in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,<sup>38</sup> in which the Federal Circuit applied the experimental use exception to the pharmaceutical industry.<sup>39</sup> Bolar used Roche's patented drug compound to develop a generic version of one of Roche's drugs.<sup>40</sup> Bolar was required by law to delay manufacturing the generic drug until Roche's patent expired; however, Bolar began the drug testing process (which sometimes takes several years) before the patent's expiration in order to obtain approval from the Food and Drug Administration (FDA).<sup>41</sup> Bolar argued that its testing of Roche's drug during that period was purely experimental, but the Federal Circuit disagreed and held that Bolar infringed Roche's patents—Bolar would not be saved by the experimental use exception.<sup>42</sup>

According to the Federal Circuit, Bolar's use of the patented drug during testing violated the plain meaning of "use" in the Patent Act.<sup>43</sup> The court noted that use of a patented invention alone, without a showing that the patent-holder suffered damage or lost sales, was sufficient to make out a case of patent infringement.<sup>44</sup> The fact that

<sup>33.</sup> Id. at 699.

<sup>34.</sup> Id. at 710.

<sup>35.</sup> Id. at 703.

<sup>36.</sup> Id. at 713.

<sup>37. 307</sup> F.3d 1351, 1361-62 (Fed. Cir. 2002), cert. denied, 539 U.S. 958 (2003); see infra Part II.B.2.

<sup>38. 733</sup> F.2d 858 (Fed. Cir. 1984), cert. denied, 469 U.S. 856 (1984).

<sup>39.</sup> Id. at 858.

<sup>40.</sup> Id. at 863

<sup>41.</sup> Id. at 860.

<sup>42.</sup> Id. at 858.

<sup>43.</sup> Id. at 863.

<sup>44.</sup> Id. at 861.

Bolar's activities, at the time of the lawsuit, caused no financial loss to Roche (since the drug had not been marketed or sold) was not sufficient to afford it immunity under the experimental use exception.<sup>45</sup> Rather, the court noted Bolar's intent to profit in the future, a disqualification from experimental use protection.<sup>46</sup>

It seemed important to the *Roche* court that Bolar's drug testing activity fell within its ordinary course of business.<sup>47</sup> The court noted that Bolar's use was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>48</sup> The court held that "unlicensed experiments conducted with a view to the adoption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention."<sup>49</sup> This language and focus on the "ordinary course of business" would later prove important in the *Madey* decision applying the experimental use exception to academic institutions. The *Roche* court emphasized that it would not allow infringing activities to be masked as experimental use when such activities have "definite, cognizable, and not insubstantial commercial purposes."<sup>50</sup> The court noted the lack of precedential support for permitting infringing activities that contributed to the infringers' business interests.<sup>51</sup>

The Federal Circuit again reaffirmed the "very narrow" scope of the experimental use exception in *Embrex, Inc. v. Service Engineering Corp.*<sup>52</sup> The plaintiff, Embrex, was the exclusive licensee of a patented machine for vaccinating chicks before they hatched.<sup>53</sup> Defendant Service Engineering designed a similar machine.<sup>54</sup> In defending against the patent infringement claim by Embrex, Service Engineering argued that its activities merely involved testing its own machine.<sup>55</sup> Holding Service Engineering liable for patent infringement, the court found these tests were conducted "expressly for commercial purposes" and did not fit within the "very narrow" experimental use exemption.<sup>56</sup>

The court reiterated that the experimental use exception would only apply to activities done "for amusement, to satisfy idle curiosity, or strictly philosophical inquiry" and would not apply to any use conducted under the "guise of scientific inquiry."<sup>57</sup> Additional clarification on the meaning of that phrase would arrive two years later in a case against Duke University.<sup>58</sup>

<sup>45.</sup> Id. at 862-63.
46. Id. at 863.
47. Id.
48. Id.
49. Id.
50. Id.
51. Id.
52. 216 F.3d 1343, 1349 (Fed. Cir. 2000).
53. Id. at 1346.
54. Id. at 1346-47.
55. Id. at 1349.
56. Id. at 1349-50.
57. Id.
58. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).

#### 2. Madey v. Duke University: Laying Down the Law for Universities

This case is significant, in part, because it was the first infringement decision by the Federal Circuit that held an academic research institution liable for infringement for using a patented technology in the course of its own research.<sup>59</sup> Indeed, many commentators believe the court rendered the exception worthless to academic institutions.<sup>60</sup> I believe the case is also significant because it was the first patent infringement action against an academic institution to reach the Federal Circuit.<sup>61</sup>

The Federal Circuit in *Madey* found Duke University liable for patent infringement when Duke continued to use Professor Madey's patented laser after he left the university.<sup>62</sup> The trial court had held that Duke's use of the patented laser for basic scientific research was not aimed at commercial ventures and was thus exempted under the experimental use exception.<sup>63</sup> However, the Federal Circuit held that Duke's own patent policies verified the use of the laser as furthering its "legitimate business objectives."<sup>64</sup> The court refused to adopt the trial court's broad interpretation of the experimental use exception as applying to any research for academic, experimental, or non-profit purposes.<sup>65</sup>

The court explained that Duke's status as a non-profit institution was not determinative, since such academic institutions frequently conduct research with little or no commercial value.<sup>66</sup> Rather, the court focused on Duke's "legitimate business objectives, including educating and enlightening students and faculty," and the university's research which "increase[s] the status of the institution and lure[s] lucrative research grants, students and faculty."

Indeed, the court characterized Duke as a business and all research done at the university as Duke's line of business, thus removing the research—and any patent infringement that occurs in the research—from the experimental use exception.<sup>68</sup> This focus on whether the activity furthered the alleged infringer's legitimate business interests is not new; rather, it is entirely consistent with prior opinions. For instance, as early as 1974, the Court of Federal Claims,<sup>69</sup> ruling on patent infringement cases against the U.S. government's use of allegedly infringing aircraft, found that the experimental use exception did not apply because the use furthered the legitimate business of the using agency.<sup>70</sup>

68. Id.

<sup>59.</sup> Id. at 1361-63.

<sup>60.</sup> See, e.g., Eisenberg, supra note 8, at 1019.

<sup>61.</sup> See discussion infra Part IV.C.

<sup>62.</sup> Madey, 307 F.3d at 1361-63.

<sup>63.</sup> Madey v. Duke Univ., 266 F. Supp. 2d 420, 426-28 (M.D.N.C. 2001).

<sup>64.</sup> Madey, 307 F.3d at 1362.

<sup>65.</sup> Id. at 1361-62.

<sup>66.</sup> Id. at 1362.

<sup>67.</sup> Id.

<sup>69.</sup> The United States Court of Federal Claims has exclusive jurisdiction over patent infringement actions against the U.S. government. See 28 U.S.C. § 1498(a) (2000).

<sup>70.</sup> See Douglas v. United States, 181 U.S.P.Q. (BNA) 170, 176–77 (Ct. Cl. Trial Div. 1974); see also Infigen, Inc. v. Advanced Cell Tech., Inc., 65 F. Supp. 2d 967, 981 (W.D. Wis. 1999) (refusing to apply experimental use exception to exempt defendant's cloning experiments because "they were done as part of the ongoing business activities of defendant . . . . "); Pitcairn v. United States, 188 U.S.P.Q. (BNA) 35, 47 (Ct. Cl. Trial Div. 1975).

Moreover, the court viewed Duke's own policies regarding the patenting of research conducted at the university as part of its business objective.<sup>71</sup> Duke was, to the court, "not shy" about attaining licenses for its patented work; such licensing revenue contributed to Duke's "legitimate business."<sup>72</sup> There seemed to be an implication that Duke intended to profit from the laser at some point in the future. The court pointed out that some of the key evidence in the case was dismissed by the district court, including a statement from Duke's laser lab web site that expressed interest in corporate partnerships and Duke's establishment of an hourly fee for any non-academic laser users.<sup>73</sup> The *Madey* decision is seen as effectively precluding academic institutions from using the experimental use exception.<sup>74</sup>

#### C. The Hatch-Waxman Act: Legislature Overturns Roche

The *Roche* decision caused an uproar because of the perceived damaging implications for generic drug makers and ultimately for consumers. If generic drugs could not be tested during the life of the patented drug, they would not be able to reach the market until years after the expiration of the patent term on the pioneer drug.<sup>75</sup> Congress stepped in to overturn *Roche*, enacting the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.<sup>76</sup>

#### 1. Description of the Hatch-Waxman Act

The Hatch-Waxman Act is a codified version of the experimental use exception for the pharmaceutical industry.<sup>77</sup> The statute, in relevant part, provides that it is not "an act of [patent] infringement to . . . use . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs . . . .<sup>778</sup> The Act provides a safe harbor, permitting drug manufacturers to perform experiments needed to obtain FDA approval of their drugs, even if those experiments are conducted during the patent life of a patented drug being tested—an otherwise infringing use.<sup>79</sup> In addition, the Act lengthens the patent term for drugs requiring FDA approval before entering the market.<sup>80</sup> It also exempts certain activities that would otherwise amount to infringement.<sup>81</sup>

The Act is intended to achieve some balance between the competing interests of the patent-holder on the one hand and those of the generic drug maker on the other. It grants an extension to the original patent-holder's patent term, since several years of

<sup>71.</sup> Madey, 307 F.3d at 1362 n.7.

<sup>72.</sup> Id. at 1363 n.7.

<sup>73.</sup> Id. at 1356 n.5.

<sup>74.</sup> See Eisenberg, supra note 8, at 1019.

<sup>75.</sup> A pioneer drug is the patented drug; a generic is the non-patented version of the pioneer drug. See Abbott Lab. v. Zenith Lab., Inc., 36 U.S.P.Q. 2d (BNA) 1801, 1805 (N.D. Ill. 1995).

<sup>76.</sup> Mueller, supra note 3, at 25.

<sup>77. 35</sup> U.S.C. § 271(e)(1) (2000).

<sup>78.</sup> Id.

<sup>79.</sup> Id. §§ 156, 271.

<sup>80.</sup> Id.

<sup>81.</sup> Id.

the patent's original term were lost during the FDA approval process and before the drug entered the market.<sup>82</sup> In exchange, generic drug manufacturers may use the original patented drug during testing, permitting the drug to complete the FDA approval process and be ready for market release as soon as the original patent expires.<sup>83</sup> The Act provides that making, using, or selling a patented invention "solely for uses reasonably related" to gathering data in order to acquire approval under the federal laws that regulate drug manufacture, use, or sale is not an act of patent infringement.<sup>84</sup>

The U.S. Supreme Court has interpreted the Act to cover more than drugs; it also covers testing of medical devices, which, like pharmaceuticals, are subject to a lengthy FDA approval process.<sup>85</sup> The Court reasoned that the sections of the Act are complementary in that all of the products eligible for a patent term extension under section 201 of the Act are also subject to section 202's exemption for early testing.<sup>86</sup> Thus, medical devices, food additives, color additives, new drugs, antibiotic drugs, infant formula,<sup>87</sup> and human biological products (all of which are subject to pre-market approval by the FDA) are covered under the testing exemption.<sup>88</sup> Accordingly, patentholders of both drugs and medical devices must tolerate the infringing activities of competitors who conduct FDA approval tests prior to the expiration of the patent terms.<sup>89</sup>

### 2. The Supreme Court Interprets the Hatch-Waxman Act

Recently, in *Merck KGaA v. Integra Lifesciences I, Ltd.*,<sup>90</sup> the U.S. Supreme Court considered early pre-clinical studies conducted by Merck that were not ultimately included in submissions to the FDA.<sup>91</sup> The Court held these studies exempt under the safe harbor provision.<sup>92</sup> The Court vacated the judgment of the Federal Circuit,<sup>93</sup> which had reasoned that the experiments did not receive safe harbor protection because they had not been included in FDA submissions and constituted merely "general biomedical research to identify new pharmaceutical compounds."<sup>94</sup>

The Supreme Court noted that early in the experimentation and testing process, it is difficult to ascertain what will ultimately be submitted to the FDA because of the trial and error inherent in the process.<sup>95</sup> The exception is generic drugs, because it is known at the outset that a particular compound, which is identical to the drug already

<sup>82.</sup> Id. § 271(e)(1).

<sup>83.</sup> Id. See generally 5 DONALD S. CHISUM, CHISUM ON PATENTS, § 16.03[1] (2004).

<sup>84. 35</sup> U.S.C. § 271(e).

<sup>85.</sup> See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671 (1990).

<sup>86.</sup> Id. at 673.

<sup>87.</sup> Id. at 674 n.6.

<sup>88.</sup> Id. at 673-74.

<sup>89.</sup> Id. at 673.

<sup>90. 545</sup> U.S. 193 (2005).

<sup>91.</sup> Id. at 195.

<sup>92.</sup> Id. at 208.

<sup>93.</sup> Id.

<sup>94.</sup> Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 866 (Fed. Cir. 2003).

<sup>95.</sup> Merck, 545 U.S. at 206.

approved, will be submitted to the FDA.<sup>96</sup> Accordingly, the Supreme Court reasoned that the rule espoused by the Federal Circuit would limit the safe harbor to generics only, an interpretation that the Court rejected.<sup>97</sup> Instead, the Court focused on the phrase "reasonably related," interpreting it broadly to cover all activity that one intending to develop a particular drug has a reasonable basis for believing may be included in a submission to the FDA if successful.<sup>98</sup> The fact that the experiment may prove unsuccessful is not relevant.<sup>99</sup>

While the Supreme Court's expansive interpretation of section 271(e)(1) represents a victory for those wishing to conduct testing in order to obtain regulatory approval before the expiration of a patent, the ruling will likely have a negative effect on drug research patents. Arguably, these research patents will lose most, if not all, of their commercial value.<sup>100</sup>

#### III. THE BAYH-DOLE ACT AND THE COMMERCIALIZATION OF ACADEMIC RESEARCH

Historically, the federal government owned all rights to research sponsored by federal funds; such research typically was not patented because it was considered "public research."<sup>101</sup> While "public research" was immediately and freely available to the public, "commercial research" funded by private investment was kept secret until patented and able to generate revenue by license.<sup>102</sup> Congress recognized that the collaboration between scientific research and business would allow rapid and efficient commercial development of basic research.<sup>103</sup>

In 1980, Congress passed the Bayh-Dole University and Small Business Patent Procedures Act (the "Bayh-Dole Act"), which allowed private ownership of patented inventions resulting from research funded by the federal government.<sup>104</sup> It permitted universities, small businesses, and nonprofit institutions to hold patents on the inventions they generated with public money.<sup>105</sup> Its purpose was to accelerate the development of inventions that would benefit the public.<sup>106</sup> The federal government retained some rights to the inventions, but assigned most of its property rights to the

<sup>96.</sup> Id.

<sup>97.</sup> Id.

<sup>98.</sup> Id. at 206-07. The Court articulated its test as follows: "At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under ... Federal law.'" *Id.* at 207.

<sup>99.</sup> Id.

<sup>100.</sup> If one can infringe drug research patents without consequence, and there is no other use for these patented tools, then there is virtually no incentive for one to invest in obtaining these patents. *See* Brief for Wisconsin Alumni Research Foundation et al. as Amici Curiae Supporting Respondents at 15-19, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (No. 03-1237) [hereinafter Wisconsin Amicus Brief].

<sup>101.</sup> See 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, 211-12 (2000).

<sup>102.</sup> Id. at 212.

<sup>103.</sup> Id. at 213.

<sup>104. 35</sup> U.S.C. §§ 200-212 (2000).

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

<sup>106.</sup> Id. § 200.

research labs.<sup>107</sup> This Act recognizes the great public value of allowing academic institutions to pursue commercial development of their federally funded research.<sup>108</sup> The Act has fueled a major change with respect to universities and patents. As one commentator notes, "universities have become players in the patent system in a way that could hardly have been imagined before the Bayh-Dole Act."<sup>109</sup>

#### A. Changes in Attitude About University Discoveries

Money changes everything. That phrase encapsulates the new trend in university research. The fact that university research now had commercial value ushered in a new attitude toward research and patenting. While at one time the premise was that basic research should be freely available to everyone, now that discoveries could have commercial value and financial rewards, it became more important to treat research as private property.<sup>110</sup> Additionally, before the Bayh-Dole Act, federally sponsored university research generally required the assignment of patents to the government and free licensing to all those interested.<sup>111</sup> Now, however, universities could keep royalties and licensing fees. As a result, a stream of revenue arrived at a time when government funds for research were decreasing and universities' need for additional funding was increasing.<sup>112</sup> On an individual level, inventors were then also able to share royalties with the university, further adding to their profit incentives, and perhaps affecting which experiments were pursued.<sup>113</sup> Together, these factors, among others, have changed patenting activity and the research business at universities.

#### B. Universities Profit From Patent Licenses

The Bayh-Dole Act can be seen as a mandate to universities to obtain patents and commercialize their inventions, a mandate that universities have taken seriously over the last twenty years.<sup>114</sup> Its impact on the business of university research is enormous. While in 1981 universities were awarded 436 patents, by 2001 that annual figure climbed to 3,203.<sup>115</sup> Sizeable revenues have also accompanied the growth in university

<sup>107.</sup> Id. § 202(c)(4) ("With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world ....").

<sup>108.</sup> See id.

<sup>109.</sup> Eisenberg, supra note 8, at 1018.

<sup>110.</sup> See Suzanne T. Michel, Comment, The Experimental Use Exception to Infringement Applied to Federally Funded Inventions, 7 HIGH TECH. L.J. 369, 378–79 (1992).

<sup>111.</sup> See generally Valoir, supra note 101.

<sup>112.</sup> See I National Science Board, Science and Engineering Indicators 2002, at O-11 (2002), available at http://www.nsf.gov/statistics/seind02/pdf/volume1.pdf. In the early 1960s, the federal government began a trend of compensating for a continually shrinking share of federal research and development funds. By 1979, the federal share fell below fifty percent and declined even more steeply during the 1990s. Since the second half of the 1980s, federal research and development actually declined after adjusting for inflation. Additionally, federal research and development was essentially flat during the past decade. *Id.*; see also Michel, supra note 110, at 379.

<sup>113.</sup> See Michel, supra note 110, at 380.

<sup>114.</sup> See Wisconsin Amicus Brief, supra note 100, at 19-21.

<sup>115.</sup> See 2 National Science Board, Science and Engineering Indicators 2004, A5-103, A5-105 (2004), available at http://www.nsf.gov/statistics/sceind04/pdf\_v2.html [hereinafter National Science Board 2004].

patents.<sup>116</sup> In 1997, universities earned about \$500 million in gross revenues from patents.<sup>117</sup> A 2002 survey of 156 colleges and universities revealed that the institutions earned almost \$1 billion in combined licensing revenues that year.<sup>118</sup>

One need look no further than the biotechnology industry over the last few years to see the strong influence of university patent ownership. "[T]he biotechnology industry as we know it today began on university campuses in the United States."<sup>119</sup> Universities have served as sources of numerous patent biomedical inventions as well as founders or affiliates of start-up firms based on their patents.<sup>120</sup> Public and private universities receive about one billion dollars in gross license revenues from their intellectual property.<sup>121</sup> For instance, the Massachusetts Institute of Technology received \$5.5 million in licensing fees in 1991.<sup>122</sup> These figures illustrate the increasing collaboration between university research and private enterprise that the Bayh-Dole Act was meant to achieve.

#### C. Universities Enforce Their Patent Rights

Along with the growth in their patent portfolios, universities have aggressively enforced their patents in court. Many of these lawsuits have led to very large settlement or damages awards. A few are mentioned here. The University of California sued Genentech and settled for \$200 million.<sup>123</sup> The University of Minnesota sued Glaxo Wellcome and won a \$300 million settlement.<sup>124</sup> Emory University just recently collected \$540 million in royalty fees (believed to be the largest settlement for a university to date) to settle litigation on some drug patents.<sup>125</sup> Several other universities including Cornell University,<sup>126</sup> Columbia University,<sup>127</sup> Harvard,<sup>128</sup> the Massachusetts

<sup>116.</sup> Universities with highly successful patents realize larger profits than most other institutions, whose licensing revenues tend to constitute a smaller part—approximately four percent—of their budget. See Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, 20 BERKELEY TECH. L.J. 1031, 1087–88 (2005).

<sup>117. 1</sup> National Science Board, Science and Engineering Indicators 2000, at 6–57 (2000), available at http://www.nsf.gov/statistics/seind00/c6/c06.pdf (During 1989–90, the reported income flows from licenses totaled a mere \$82 million, reaching \$483 million in 1997.).

<sup>118.</sup> Ass'n of Univ. Tech. Managers, AUTM Licensing Survey: FY 2002 62 (Ashley J. Stevens ed., 2003), available at http://www.autm.net/events/file/surveys/02\_abridged\_survey.pdf [hereinafter AUTM Licensing Survey]; see also Susie Poppick, Yale Keeps Patent Stats Secret, YALE DAILY NEWS, Dec. 8, 2004, available at http://www.yaledailynews.com/article.asp?AID=27658.

<sup>119.</sup> Wisconsin Amicus Brief, supra note 100, at 3.

<sup>120.</sup> John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* Patents in the Knowledge-Based Economy 285, 286 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., *Effects*].

<sup>121.</sup> AUTM Licensing Survey, supra note 120, at 62.

<sup>122.</sup> Michel, supra note 110, at 380 n.59.

<sup>123.</sup> Marcia Barinaga, Genentech, UC Settle Suit for \$200 Million, 286 SCIENCE 1655 (1999).

<sup>124.</sup> Regents of the Univ. of Minn. v. Glaxo Wellcome, Inc., 58 F. Supp. 2d 1036, 1036 (D. Minn. 1999).

<sup>125.</sup> Meredith Hobbs, A \$540M Payday Caps Patent Fight, NAT'L L.J., Aug. 8, 2005, at 8.

<sup>126.</sup> Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004) (action for patent infringement brought by plaintiffs including Creative Technologies, Inc., a representative of the University of Colorado and Cornell University).

<sup>127.</sup> In re Columbia Univ. Patent Litig., 330 F. Supp. 2d 18, 18 (D. Mass. 2004).

<sup>128.</sup> Ariad Pharms., Inc. v. Eli Lilly & Co., No. 02-11280-RWZ, 2004 U.S. Dist LEXIS 3170, at \*1-\*2

Institute of Technology,<sup>129</sup> and University of Rochester<sup>130</sup> have also sued to enforce their patents. Sometimes, a university may even appear as a co-plaintiff with a corporation on one patent and a defendant against it on another.<sup>131</sup> In 2004, the University of Colorado and Cornell University were awarded a \$2.1 million judgment and \$4.5 million in damages and interest against Laboratory Corporation of America.<sup>132</sup> Interestingly, universities do not appear to be suing each other for patent infringement.<sup>133</sup>

#### D. Relationships with Industry

Universities are now partners and collaborators with industry. For instance, a few years after passage of the Bayh-Dole Act, a study revealed that industry funded about twenty-five percent of all biotechnology research at universities.<sup>134</sup> Today, that number has likely increased in all areas.<sup>135</sup>

Companies enjoy this access to university researchers as it enhances their competitive position. Industry involvement takes various forms: (i) the university could be under contract to conduct specific experiments; (ii) the university could provide continuing education to a company's researchers; (iii) the university could have a grant directed at a specific researcher or project; (iv) the university may form a review board that includes corporate members to decide which university projects will be funded; or (v) the university's professors may enter commercial ventures (such as starting companies or partnering with venture capitalists to commercialize research).<sup>136</sup>

132. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004).

136. Michel, *supra* note 110, at 381.

 <sup>(</sup>D. Mass. Mar. 3, 2004) (action for patent infringement brought by plaintiffs including MIT and Harvard).
 129. Mass. Inst. of Tech. v. Lockheed Martin Global Telecomms., Inc., 251 F. Supp. 2d 1006, 1007 (D. Mass. 2003); Akamai Techs., Inc. v. Speedera Networks, Inc., No. 02-10188-RWZ, 2002 U.S. Dist. LEXIS
 15903, at \*1-\*2 (D. Mass. Aug. 26, 2002).

<sup>130.</sup> Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216, 220 (W.D.N.Y. 2003).

<sup>131.</sup> Compare Eli Lilly & Co. v. Teva Pharms. USA, Inc., No. IP 02-0512-C-B/S, 2004 U.S. Dist. LEXIS 14724, at \*2-\*3 (S.D. Ind. July 29, 2004) (action by Eli Lilly & Co. for pharmaceutical patent infringement with MIT as an involuntary plaintiff), with Ariad Pharms., Inc., 2004 U.S. Dist. LEXIS 3170, at \*1-\*2 (action by MIT against Eli Lilly & Co. for pharmaceutical patent infringement). As a general rule, a patent owner must join the exclusive licensee of the patent in any infringement action brought by the licensee. See Erbamont Inc. v. Cetus Corp., 720 F. Supp. 387, 393 (D. Del. 1989).

<sup>133.</sup> See infra Part IV.C. The infringement suits in which universities are defendants tend to be declaratory judgment actions where the plaintiff seeks a ruling that the university's patent is invalid (after the university has filed or threatened to file an infringement action). See, e.g., Medlmmune, Inc. v. Centocor, Inc., 409 F.3d 1376, 1378 (Fed. Cir. 2005); Synbiotics Corp. v. Regents of the Univ. of Cal., Nos. 93-1253, 94-1079, 1994 U.S. App. LEXIS 23902, at \*1 (Fed. Cir. Aug. 29, 1994); New Star Lasers, Inc. v. Regents of the Univ. of Cal., 63 F. Supp. 2d 1240, 1241 (E.D. Cal. 1999).

<sup>134.</sup> David Blumenthal et al., Industrial Support of University Research in Biotechnology, 231 SCIENCE 242, 244 (1986).

<sup>135.</sup> Kenneth Sutherlin Dueker, Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies, 52 FOOD & DRUG L.J. 453, 479 (1997).

All of the earliest genetic engineering companies were founded by professors who completed the initial research in university laboratories. For instance Genentech, co-founded by Herbert Boyer to exploit the Cohen-Boyer gene splicing patent, did not have a laboratory in its early stages, so Boyer's campus laboratories at UCSF were used.

#### IV. THE PRACTICAL REALITY: RESEARCH WILL LIVE ON

Despite the cries of impending doom, the *Madey* decision does not signal the death of research and innovation in universities. In reality, the decision will probably have little effect on the way researchers conduct their day-to-day business.<sup>137</sup> This is mostly because the research marketplace will continue to guide and control the conduct of researchers and patent-holders (especially considering the frequent role reversal of these parties), thus providing an appropriate balance between enforcing patent rights and allowing innovation. In a recent survey, none of the respondents reported having to discontinue projects because of problems involved in obtaining intellectual property rights for their research.<sup>138</sup> Instead, they have adopted "working solutions" to intellectual property issues in their research.<sup>139</sup>

One of the ironies of the controversy surrounding the experimental use exception is that the *Madey* decision is both a blessing and a curse for universities. On the one hand, universities criticize the narrowness of the exception, particularly its elimination of the long held (albeit erroneous) belief in their immunity from patent infringement for research activities. On the other hand, however, as major patent-holders, universities benefit from a strict and narrow interpretation of the exception. Millions of dollars in licensing revenues and royalties would be lost, for instance, if all research were exempted from infringement until commercialized.

There are several considerations, discussed more fully below, that alone and in conjunction effectively self-regulate the business of university research. These factors permit university researchers to experiment without much fear of suit, particularly where their activities are not commercial or profit-making in nature. Further, the innovation process in practice, especially to the extent that universities are involved, is not one of exclusive competition but rather one of cooperation and sharing of research information.<sup>140</sup> Together, these factors ensure that research and innovation will continue to thrive.

<sup>137.</sup> See Cristina Weschler, Note, The Informal Experimental Use Exception: University Research After Madey v. Duke University, 79 N.Y.U. L. REV. 1536, 1552–62 (2004) (discussing how non-legal solutions protect university research).

<sup>138.</sup> John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021 (2003) [hereinafter Walsh et al., *Working*].

<sup>139.</sup> Id. These solutions include (i) obtaining licenses from patent-holders, (ii) developing and participating in public and quasi-public databases that make information available, (iii) inventing around patents, (iv) going overseas, (v) filing suit against patent-holders (e.g., seeking a declaratory judgment), and (vi) using the technology without a license (a practice that is admittedly very common among university researchers). Id.

<sup>140.</sup> Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2181 (1991). Obviously, there are occasions when the general culture of sharing breaks down. In *Madey v. Duke University*, for instance, Madey chose to sue his former employer, rather than allow it to continue to use his lasers. 307 F.3d 1351, 1352 (Fed. Cir. 2002). While we may not be privy to the specific motivations and deliberations in that case, one can imagine that there may have been underlying difficulties in their relationship, perhaps leading to, or as a result of, Madey's separation from employment with the university. Absent these kinds of tensions, however, the spirit of cooperation ought to prevail.

#### MAINE LAW REVIEW

#### A. The Effect of Merck v. Integra

The ultimate effect of the *Merck* opinion on the common law experimental use exception is that it provides a wide exemption that serves to enlarge the experimental use exception when the research involves a use protected under the Hatch-Waxman Act.<sup>141</sup> Interestingly, one of the beneficiaries of the opinion will be universities. To the extent the opinion can be read as permitting all drug experimentation, not only for generics but for pioneer drugs as well,<sup>142</sup> research universities benefit directly when their research includes the development of new drugs. Moreover, because the safe harbor provision of the Hatch-Waxman Act extends not only to submissions to the FDA but also to research reasonably related to submission under a federal program, *Merck* casts a wide net of exemptions, all to the benefit of research universities.<sup>143</sup> Granted, the opinion does not eradicate the narrow effects under *Madey*, in that it does not cover all of the kinds of research that may be conducted at universities, but it does provide some immunity to areas that heretofore would not have been protected under the experimental use exception.

#### B. Licensing: Just Ask Nicely

It has become commonplace among university researchers to use patented devices without seeking a license.<sup>144</sup> At the risk of stating the obvious, university researchers (like all others) need to ask for a license in order to use a patented invention as required by law. Although additional costs may accompany such a request, to complain about those costs does not provide a sufficiently compelling reason to grant an exception. Just as a long-time tax evader earns no sympathy when the time arrives to make payments to the Internal Revenue Service, universities' complaints about now having to pay licensing fees are unpersuasive.

Licensing is a routine and integral part of the intellectual property business.<sup>145</sup> Indeed, most universities already have technology transfer offices that handle intellectual property issues, including licensing arrangements,<sup>146</sup> with an indicator of success measured by licensing revenue.<sup>147</sup> Granted, seeking out and obtaining licenses may prove cumbersome; however, such difficulty in and of itself should not serve as a reason for noncompliance.<sup>148</sup>

<sup>141.</sup> See supra Part II.C.1.

<sup>142.</sup> A pioneer drug is the patented drug; a generic is the non-patented version of the pioneer drug. See Abbott Labs. v. Zenith Labs., 934 F. Supp. 925, 931 (N.D. Ill. 1995).

<sup>143.</sup> The Act has already been interpreted to cover medical devices. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 664, 679 (1990).

<sup>144.</sup> Walsh et al., *Working, supra* note 138, at 1021. In the Walsh study, all of the university respondents admitted using patented research tools without permission at times.

<sup>145.</sup> See Carlyle C. Ring, Jr., An Overview of the Virginia UCITA, 8 RICH. J.L. & TECH. 1, 8 (2001), available at http://law.richmond.edu/jolt/v8il/article1.html.

<sup>146.</sup> See Kapczynski et al., supra note 116, at 1080-81.

<sup>147.</sup> Id. at 1085.

<sup>148.</sup> Universities may be able to devise a relatively accessible procedure for their researchers to obtain licenses by posting guidelines or forms on their websites. *See, e.g.*, Univ. of Tex. System of Intellectual Property Reference Page, http://www.utsystem.edu/ogc/intellectualproperty/index.htm (last visited Mar. 6, 2007).

Further, the fear that research will be hampered because researchers will need to spend all their time tracking down patents and negotiating licenses is misplaced. In practice, very few licenses need to be negotiated on any given project.<sup>149</sup> Although many potentially applicable patents may need to be reviewed at the outset, of those, only a few will actually be relevant, and in the end, a handful or less will need to be licensed.<sup>150</sup> With respect to costs, universities also have an advantage in that many patent-holders provide discounted licenses to universities, often for less than half the market rate.<sup>151</sup>

There also does not appear to be any evidence that patent-holders will impede research by unreasonably refusing to grant licenses to universities.<sup>152</sup> To the contrary, denied access to intellectual property rights very rarely leads to the termination of a worthwhile project.<sup>153</sup> Rather, other considerations, such as lack of confidence in the technical success of the project, market demand, and limited internal resources, account for the decision to discontinue a project.<sup>154</sup> Even in the rare instance where a project might be terminated because of licensing difficulties, one commentator has suggested that the social cost of not pursuing projects is low, given the vast array of other available projects.<sup>155</sup>

Another market force facilitating cooperation among researchers seeking licenses is the repetitive nature of the licensing game. A licensing negotiation between a university and a patent-holder is often not a one-time event; the parties may find themselves in the future negotiating (or may already have negotiated) other patents, and it is important that they show respect for the quid pro quo by maintaining a good relationship and remaining reasonable.<sup>156</sup>

Licensing could have avoided the litigation in both *Madey* and *Merck*. In *Madey*, Duke argued that it had a license under grants received by the federal government, but none of the pertinent contracts defined the scope of these rights.<sup>157</sup> Accordingly, the university's rights to the invention were not clearly delineated. The better practice would have entailed negotiating a license from Madey, the inventor, to Duke at the outset of Madey's employment.<sup>158</sup> In *Merck*, the parties attempted but failed to reach a license agreement.<sup>159</sup> To the extent such failure occurred because the patent-holder

<sup>149.</sup> Walsh et al., Effects, supra note 120, at 294.

<sup>150.</sup> Id. at 294-95.

<sup>151.</sup> Weschler, supra note 137, at 1553-55.

<sup>152.</sup> See, e.g., Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 YALE L.J. 177, 219 (1987); Sandstrom, supra note 5, at 1103.

<sup>153.</sup> Walsh et al., Effects, supra note 120, at 298.

<sup>154.</sup> Id. at 298, 304. One respondent in the Walsh survey said, "I am hard pressed to think of a piece of research that we haven't done because of blocked access to a research tool." Id. at 298.

<sup>155.</sup> See id. at 305.

Some respondents have suggested that the value of targets has actually declined substantially because companies can't exploit all of the targets they have, and so firms are more willing to license some of their targets, or abandon some of their patents and let the inventions shift to the public domain, because maintaining large portfolios of low-value patents is expensive.

Id. at 305.

<sup>156.</sup> Id. at 326.

<sup>157.</sup> Madey v. Duke Univ., 307 F.3d 1351, 1364 (Fed. Cir. 2002).

<sup>158.</sup> See infra note 165 and accompanying text.

<sup>159.</sup> See Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863 (Fed. Cir. 2003).

was unreasonable, it provides a lesson to patent-holders in licensing negotiations: be cooperative, or you may lose big, not only in the eventual outcome, but also through the very expensive and risky litigation process.<sup>160</sup>

The National Academy of Sciences (the Academy), which has no legal authority but wields influence over particular scientific journals, issued a decree in early 2003, urging, among other things, the licensing of patented materials.<sup>161</sup> The organization also encourages patent-holders to issue equal license fees to everyone, regardless of whether the request comes from academia or industry because "[t]here is no clear line between the 'for-profit sector' and 'academic' research."<sup>162</sup> When granting exclusive licenses to industry, however, universities must be mindful that they may want to reserve some of their rights in order to permit future licensing to those in the academic community.<sup>163</sup> While it is too early to tell if the scientific community will abide by its own policy, the Academy's decree reflects a sign of the cooperative spirit that underlies academic research.

#### C. Tolerating Universities' Patent Infringement

*Madey* is the first case in which a university was sued for patent infringement.<sup>164</sup> That telling statement supports my argument that universities are not likely to be sued for infringement. Even in *Madey*, the facts are unusual because the case arose not out of the typical situation where a competitor sues another, but out of an employer-employee dispute.<sup>165</sup>

The points below help to explain why universities are unlikely to be sued for patent infringement. Indeed, universities tend to ignore notification of infringement letters, particularly when they are not engaging in commercially related research.<sup>166</sup> One commentator notes that "[s]o long as the university is not generating revenue based on the patented technology, universities appear to be largely left alone, although some firms will send letters."<sup>167</sup> Universities are also not inclined to sue each other, especially when the alleged infringer is not commercializing the innovation.<sup>168</sup>

<sup>160.</sup> For many plaintiffs, the risk that the patent at suit will be invalidated is a high and very real risk. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216, 234 (W.D.N.Y. 2003) (invalidating the university's drug patent).

<sup>161.</sup> Committee on Responsibilities of Authorship in the Biological Sciences, Nat'l. Acad. Sci., Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences 7 (2003), *available at* http://fermat.nap.edu/books/0309088593/html/R1.html (last visited Mar. 6, 2007).

<sup>162.</sup> Id. at 67.

<sup>163.</sup> See Kapczynski et al., supra note 116, at 1076.

<sup>164.</sup> The infringement suits in which universities are defendants tend to be declaratory judgment actions where the plaintiff seeks a ruling that the university's patent is invalid (after the university has filed or threatened to file an infringement action). *See, e.g.*, MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376, 1378 (Fed. Cir. 2005); Synbiotics Corp. v. Regents of the Univ. of Cal., 32 U.S.P.Q. (BNA) 1835, 1836 (Fed. Cir. 1994); New Star Lasers & Laser Aesthetics, Inc. v. Regents of the Univ. of Cal., 63 F. Supp. 2d 1240, 1241 (E.D. Cal. 1999); *see also supra* note 124.

<sup>165.</sup> Usually the employer retains the patent rights to inventions, but in this case the inventor owned the rights. When he changed employers, there was no license given to the new employer. See RONALD B. HILDRETH, PATENT LAW: A PRACTITIONER'S GUIDE § 1:8.5 (3d ed. 1999).

<sup>166.</sup> See Walsh et al., Effects, supra note 120, at 317.

<sup>167.</sup> Id. at 319.

<sup>168.</sup> See id. at 327.

#### 1. The Honor System

Common sense dictates that it is simply not possible for patent-holders to monitor the activities of researchers and scientists in their private labs. The system relies on an honor system of sorts requiring the researchers themselves to come forward, seek out the patent-holder, and ask for permission. When research becomes public (generally through publication) and/or commercialized, infringement becomes easier for a patentholder to detect. In addition, many researchers may choose to wait until that time to seek permission from patent-holders.<sup>169</sup> In some cases, the six-year statute of limitations<sup>170</sup> may expire before infringement is even discovered.<sup>171</sup>

#### 2. Difficulties of Litigation

While in theory it may appear easy (based on the definition of infringement) for a patent-holder to vindicate her rights where a university or other party has infringed them, the reality is far different. This is due to the costs, both financial and otherwise, of patent litigation. For starters, a potential plaintiff contemplating filing suit must consider the time and cost involved; such a suit may not be resolved for years and could cost millions of dollars in attorney's fees alone, with no guarantee of success.<sup>172</sup>

It is also important that the patentee be able to recover significant damages in order to make this endeavor worthwhile. Thus, where a patented invention, although infringed, has not generated profits or proven commercially successful, it simply does not make sense to pursue aggressively an infringement claim. This grants universities de facto immunity for purely research-related infringement activities that do not generate revenues for the institution.

In addition to the time and energy one expends worrying about each step of the case, there is also the time drain on all the individuals associated with the patented invention. For instance, everyone in the patent-holder's organization may be involved in discovery, searching and copying years of files and preparing and responding to written and oral discovery.<sup>173</sup> The patentee also takes the risk that the patent at suit will be invalidated, an occurrence that is not uncommon.<sup>174</sup>

#### 3. University Relationships Are Important

For a host of intangible reasons, a culture of not suing universities appears to exist. In part, potential litigants fear that such suits will result in bad publicity because "it is

<sup>169.</sup> See Richard C. Levin et al., Appropriating the Returns from Industrial Research and Development, BROOKINGS PAPERS ECON. ACTIVITY: MICROECON. 783, 807 (1987).

<sup>170. 35</sup> U.S.C. § 286 (2000).

<sup>171.</sup> Walsh et al., Working, supra note 138, at 1021; see also David J.F. Gross & Lee Pulju, Ten Things to Consider Before Sending a Patent Infringement Warning Letter, 15 J. PROPRIETARY RTS. 12, 13 (2003).

<sup>172.</sup> See Walsh et al., Effects, supra note 120, at 315.

<sup>173.</sup> See id.

<sup>174.</sup> See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205-07 (1998) (finding that forty-six percent of patents were invalidated in cases litigated between 1989 to 1996).

not good form to sue researchers in academic institutions and stifle their progress."<sup>175</sup> Industry also has much to gain by developing trusting relationships with university researchers.<sup>176</sup>

Some scientists even admitted that they welcome a low level of patent infringement because such "background infringement" can contribute to the value of their invention by generating interest in the new technology.<sup>177</sup> This is because of the belief that those who utilize a particular new technology to solve a research problem are likely to continue to use that technology—and share it with others—in the future. Thus, when the "background infringement" becomes too great, the patent-holders assert their property rights against the infringers by offering a license to use the invention. The infringing scientists are then forced either to obtain a license for the technologies they have used in their research methods or search for new methods to solve the problems.<sup>178</sup>

#### 4. Sovereign Immunity for State Universities

A narrow experimental use exception poses an even lower threat of impending doom to academic researchers given the immunity conferred on a significant number of universities because of their status as public institutions.<sup>179</sup> Trying to avoid this result, Congress (using its Article I powers) passed legislation in 1992 that expressly abolished sovereign immunity under the Eleventh Amendment for states and state employees who engage in patent infringement.<sup>180</sup> In 1999, however, the Supreme Court held the law unconstitutional in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.<sup>181</sup> The Court reasoned that state sovereign immunity can be abrogated only under the Fourteenth Amendment, not under Congress's Article I powers.<sup>182</sup> Since Congress did not provide a basis under the Fourteenth Amendment for abolishing state immunity from patent infringement liability, the law was unconstitutional.<sup>183</sup> Accordingly, state entities, including state universities, are immune from patent infringement suits.

<sup>175.</sup> Walsh et al., Effects, supra note 120, at 325.

<sup>176.</sup> In the Walsh survey, one respondent from a private firm noted:

We rely on lots of outside collaborations with academic labs. Our scientists want to feel on good terms with the academic community. If you start suing, it breaks down the good feeling. We give out our research tools for free, frequently. All we ask is, if you invent anything that is directly related to the tool, you allow us the freedom to practice.

Id. at 326.

<sup>177.</sup> See id.

<sup>178.</sup> See Josh Lerner, Patenting in the Shadow of Competitors, 38 J.L. & ECON. 463, 463 (1995).

<sup>179.</sup> Approximately forty percent of degree granting postsecondary institutions are public. See THOMAS D. SYNDER ET AL., U.S. DEP'T OF EDUC., DIGEST OF EDUCATION STATISTICS 2003, at 310 tbl.246 (2004), available at http://nces.ed.gov/pubs2005/2005025.pdf (degree-granting institutions, by control and type of institution: 1949-1950 to 2002-2003).

<sup>180.</sup> Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, § 2(a)(2), 106 Stat. 4230, 4230 (1992) (codified at 35 U.S.C. § 296 (2000)).

<sup>181. 527</sup> U.S. 627, 647-48 (1999).

<sup>182.</sup> Id. at 637.

<sup>183.</sup> Id. at 639-43.

This ruling is particularly significant here because public universities sit front and center in patenting activity. Approximately sixty percent of the patents issued to universities in 2001 went to public universities.<sup>184</sup> Thus, their immunity from infringement damages is very significant. For all practical purposes, these universities essentially have wide latitude to infringe, and patent-holders have little recourse.<sup>185</sup> An experimental use exception—narrow or broad—has less impact on state universities as defendants because, unlike their private counterparts, they are insulated.<sup>186</sup> They are in the rare and enviable position of having the best of both worlds: they can sue others for patent infringement but cannot be sued for the same practice.

Allowing state universities sovereign immunity from patent infringement may have the unforeseen consequence of indirectly granting immunity to private industry collaborators who shift resources to the university for just such protection.<sup>187</sup> It is currently unknown what level of state funding or control will make a collaborative endeavor an instrumentality of the state (and thus protected under state immunity), rather than a disguised extension of the private industry collaborator.<sup>188</sup>

#### V. THE EXEMPTION IS APPROPRIATELY NARROW

This Article does not support a judicial broadening of the experimental use exception. In order for the exception to remain limited and thereby make meaningful a patent-holder's rights to exclusivity, the exception must be kept narrow. To do otherwise would risk enlarging the exception to a point where it swallows the rule prohibiting patent infringement. Even recognizing that, as with most rules, there may be a sufficiently compelling reason to create an exception to the exception, there has been no evidence presented indicating why research universities deserve special treatment in this area. To the extent that the business of a university, as it pertains to research, has become indistinguishable from the business of a commercial research lab, it seems only fair that the rules should apply equally to both.

Infringement is not a matter of degree. Courts have made clear that there is no such thing as *de minimis* infringement.<sup>189</sup> Thus, any exceptions to infringement should be similarly specific and not open to a question of degree or to an evaluation of merit. In particular, where a university has infringed a patent through its research activities,

<sup>184.</sup> National Science Board 2004, *supra* note 115, at A5-105. The top ten patenting public universities from 1991 to 2001 were University of California, University of Texas, University of Wisconsin, University of Florida, State University of New York, University of Michigan, Iowa State University, University of Minnesota, Michigan State University, and University of Washington. *Id.* 

<sup>185.</sup> However, under the *Ex parte Young* doctrine, state workers may be sued in federal court in their individual capacity. See Ex parte Young, 209 U.S. 123, 154 (1908); see also Peter S. Menell, Symposium on New Direction in Federalism: Economic Implications of State Sovereign Immunity from Infringement of Federal Intellectual Property Rights, 33 LOY. L.A. L. REV. 1399, 1404 (2000). Further, although patentholders cannot obtain monetary compensation from the state, they may obtain injunctive relief. See id. However, injunctive relief against a state university under Eleventh Amendment state immunity would still make litigation expensive and time-consuming. Id.

<sup>186.</sup> For further discussion about state universities' immunity from intellectual property claims, see Traci Dreher Quigley, Comment, Commercialization of the State University: Why the Intellectual Property Protection Restoration Act of 2003 Is Necessary, 152 U. PA. L. REV. 2001, 2002 (2004).

<sup>187.</sup> Mueller, supra note 3, at 33-34.

<sup>188.</sup> See id. at 36.

<sup>189.</sup> See, e.g., Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984).

it should not be up to the courts to decide and assess the nature of the infringement, the intent of the researcher, or whether the infringement led to the discovery of a commercially viable product.<sup>190</sup>

Moreover, a broad experimental use exception would provide disincentives to invest in patenting and innovation. Weakening a patentee's control over her patented invention deprives her of the pecuniary benefits associated with the patent, thus reducing the returns from her investment in the invention. Further, a broad exception would also discourage investors from devoting capital resources to research and development projects that could have yielded future returns from a patent.<sup>191</sup>

#### A. Patenting Promotes Innovation and the Public Good

Innovation is important not only for commercial profits but also because it advances the public good. The patent system encourages innovation by rewarding the substantial investments necessary for research and development. It promotes invention by granting the inventor an exclusive right to exclude others from her invention and giving her the ability to profit from it. Patenting also leads to greater efficiency by encouraging the invention of new and better products.<sup>192</sup>

In addition, the patent system promotes the development and commercialization of inventions. There are several stages between the initial invention of a product and the commercial development of the product to a point where it is ready for market. Getting from one point to the other is costly and risky.<sup>193</sup> By preventing others from using the invention for a certain period of time, the patent system permits the inventor to recoup the costs of developing the product. But for these exclusive rights, free-riders may take advantage of other's inventions, without having expended the resources for development.<sup>194</sup> Free-riding can hurt the inventor's ability to realize a return on her investment.<sup>195</sup>

The disclosure required by the patent system<sup>196</sup> is a further benefit to society. It requires inventors to make information publicly available that ordinarily would remain undisclosed as a trade secret. This benefits both the public and the inventor. It benefits the public by helping to avoid needless duplication of efforts.<sup>197</sup> For instance, a competitor may learn the results of a certain experiment and be more accurately informed about whether to pursue the project. Competitors also learn through patent disclosures what technology is available for licensing and cross-licensing, leading to a more efficient option than developing the technology itself.<sup>198</sup>

<sup>190.</sup> Any such analysis should be legislatively defined, as in the Hatch-Waxman Act. See infra Part V.D.

<sup>191.</sup> See Jordan P. Karp, Note, Experimental Use as Patent Infringement: The Impropriety of a Broad Exception, 100 YALE L.J. 2169, 2181 (1991).

<sup>192.</sup> WARD S. BOWMAN JR., PATENT AND ANTITRUST LAW 2-3 (1973).

<sup>193.</sup> Michel, supra note 110, at 392.

<sup>194.</sup> Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & ECON. 265, 266 (1977).

<sup>195.</sup> See Ben T. Yu, Potential Competition and Contracting in Innovation, 24 J.L. & ECON. 215, 237 (1981).

<sup>196. 35</sup> U.S.C. § 112 (2000).

<sup>197.</sup> See Michel, supra note 110, at 392-93.

<sup>198.</sup> See id. at 395-96.

As to the inventor, were she to keep the information as a trade secret rather than obtain a patent, she takes on greater risks. There is the risk, for example, of having the information disclosed and losing the trade secret protection, as well as the risk that someone else will independently develop the invention (in which case the inventor would be without recourse).<sup>199</sup> Weakening patent protection would lead more inventors to choose trade secret protection, the secrecy of which does not promote innovation.<sup>200</sup>

#### B. The Case for Expansion Is Not Persuasive

For those who advocate expansion of the experimental use exception, the underlying reason appears to be the belief that such expansion will promote progress and innovation. Other than the theoretical supposition that a narrow experimental use exception will lead to less innovation, there has been no demonstrable evidence that such is the case in practice. Even major research universities concede that "the more one limits the patent rights conferred by Congress, the less one promotes the progress of science."<sup>201</sup> Similarly, the Patent and Trademark Office opposed legislation broadening the experimental use exception because it would diminish the "strong incentive provided by the patent system."<sup>202</sup>

The status quo (a narrow experimental use exception) appears to have had a positive effect on research and innovation. Our patent laws are based on the notion of exclusivity and derive from the Constitution, which authorizes Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>203</sup> The premise that a person will be motivated to innovate because the patent laws will reward him for having expended the time and resources underlies our system. One need look no further than the biomedical activity over the last two decades, for instance, to see the impact that patents have had on innovation and commercialization.<sup>204</sup> Patents have also proven critical to the large increase in biotechnology start-up companies over the last few years, and it seems logical that they will continue to spur growth and innovation in many areas.<sup>205</sup>

The process of obtaining a patent is expensive and time consuming.<sup>206</sup> In order to be worthwhile, the right to exclude others (and the attendant royalties and other financial benefits) must be meaningful—it cannot be so filled with holes and exceptions that the benefit to the patent-holder is outweighed by the benefits to the general public. At a minimum, allowing unlicensed use of a patent deprives the patent-

<sup>199.</sup> See id. at 391-92.

<sup>200.</sup> See id. at 396.

<sup>201.</sup> Wisconsin Amicus Brief, supra note 100, at 11.

<sup>202.</sup> H.R. REP. NO. 101-960, at 8 n.25 (1990).

<sup>203.</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>204.</sup> Walsh et al., Effects, supra note 120, at 285.

<sup>205.</sup> Id. at 286-87.

<sup>206.</sup> See Vance Franklin Brown, Comment, The Incompatibility of Copyright and Computer Software: An Economic Evaluation and a Proposal for a Marketplace Solution, 66 N.C. L. REV. 977, 981 (1988) (stating that obtaining a patent is an expensive process that can often take up to five years); see also Raymond E. Vickery, Jr., The Laws and Outer Space: Intellectual Property, 4 J.L. & TECH. 9, 10 (1989) (noting that obtaining a patent can take a number of years and cost thousands of dollars).

holder of royalties. The patentee is contributing something of value to research, even if that contribution consists of negative information, such as findings indicating that something does not work.<sup>207</sup>

If the desire to expand the experimental use exception stems from general dissatisfaction with the patent laws as they exist today, engaging the courts in that battle is a misguided approach. If the system is in need of an overhaul, then reformers should seek to overhaul the system (which seems best done legislatively) rather than eviscerate the exemption. Strong patent enforcement is good for consumers because it provides a valuable incentive for innovation.<sup>208</sup> As discussed below, Congress should only step in to chip away the rights of patent-holders when it determines that a compelling need has been established in a particular area.

#### C. The Scope of Proposals for Expansion Is Hard to Define

Among those who favor expansion, there does not appear to be a clear consensus on the precise parameters of the infringement exemption. They seem to have a difficult time defining precisely where to draw the line in the delicate balance between protecting the patent-holder's rights and fostering research and innovation.<sup>209</sup> Should the rule be that all research universities are exempt, that only research tools are exempt, or that a particular type of research is exempt?

Some have proposed the rule that no patent infringement occurs as long as the experimenter is an academic or other non-profit research institution.<sup>210</sup> However, if the researcher develops a commercially patented invention, then the researcher should pay royalties to the patent-holder for any patents used in the design.<sup>211</sup> These proposals fail to clearly define or identify the point at which a commercialized product has been created for the purpose of requiring the royalty payments. Would it occur at the marketing stage, the product testing stage, the order solicitation stage, or some later stage?

Given the ties between universities and industry discussed above, this expansion may pose another problem by allowing corporations to circumvent the experimental use exception due to their affiliation with a university on a particular project. In other words, had the identical research been conducted in the corporation's laboratory, it would have fallen outside of the experimental use exception. However, conducting the same corporate-sponsored research in the university's laboratory provides a protective cloak.

The proposals for expansion also appear to exempt from infringement a researcher who uses a patented device for its intended purpose as a tool for conducting research.<sup>212</sup> To allow this kind of infringement simply because the tool was used in a university's research lab (the patentee's market) completely circumvents and

<sup>207.</sup> See Michel, supra note 110, at 395.

<sup>208.</sup> John Shepard Wiley Jr. et al., The Leasing Monopolist, 37 UCLA L. REV. 693, 715 n.84 (1990).

<sup>209.</sup> See, e.g., Eyal H. Barash, Comment, Experimental Uses, Patents, and Scientific Progress, 91 Nw. U. L. REV. 667, 699-700 (1997); Caruso, supra note 5, at 220; Derzko, supra note 5, at 366-367; Strandburg, supra note 5, at 138-146; Sandstrom, supra note 5, at 1106-08.

<sup>210.</sup> See, e.g., Barash, supra note 209, at 667, 699-700; Sandstrom, supra note 5, at 1106-08. 211. Id.

<sup>212.</sup> See infra note 214.

eviscerates one's patent rights. Even universities themselves who hold a large number of these patented research tools would have to concede that, at the very least, such a program would not be desirable because it would cause them to lose royalty payments.

Others have proposed or debated a compulsory licensing scheme, which includes some variation of government mandated permission to use a patented device without consent and the payment of royalties to the patent owner.<sup>213</sup>

Finally, there has been much debate about biomedical research tools and precisely how a special exemption should protect them.<sup>214</sup> It seems, however, that the notion of allowing free research (i.e., without the alleged burdens of obtaining permission) and later payment of royalties only if the research has led to a commercialized product is already the de facto rule. It is highly unlikely that a patent-holder will discover infringement or even sue an early stage researcher because, among other reasons, the damages would prove too small to justify the cost of the litigation.<sup>215</sup> Rather, serious negotiations between the researcher and the patentee occur toward the later stages of the product development process, because at that point they both have greater reasons and incentives to strike a deal. To the extent that university labs continue to resemble their commercial counterparts, justifying special treatment for universities will become even more difficult.

There is one further view that deserves discussion: the suggestion that, like copyright law, there should be a fair use exemption to patent law.<sup>216</sup> The doctrine of fair use, part of the 1976 Copyright Act, permits others to use the copyrighted material in a reasonable manner without consent.<sup>217</sup> Thus, the argument would go, where use occurs in the context of education, research, or other socially valuable activities, a fair use exception to patent infringement (i.e., a broader experimental use exception) makes sense. Even without undertaking an exhaustive review and analysis of the fair use doctrine, however, it does not seem to be the kind of model that patent law should emulate.

The fair use doctrine has been quite troublesome in copyright law and has engendered extensive litigation (about ten times more cases than the experimental use

2007]

<sup>213.</sup> See, e.g., Cole M. Fauver, Comment, Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come, 8 NW. J. INT'L. L. & BUS. 666 (1988); Alan M. Fisch, Comment, Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem, 34 JURIMETRICS J. 295 (1994); Paul Gormley, Comment, Compulsory Patent Licenses and Environmental Protection, 7 TUL. ENVTL. L.J. 131 (1993); Strandburg, supra note 5, at 138-46.

<sup>214.</sup> The research tool discussion is beyond the scope of this Article. However, for additional reference, see, e.g., Derzko, *supra* note 5, at 347; Eisenberg, *supra* note 8, at 1084-86; Mueller, *supra* note 3, at 1; Strandburg, *supra* note 5, at 81.

<sup>215.</sup> See supra Part IV.C.1-2.

<sup>216.</sup> See, e.g., Maureen A. O'Rourke, Toward a Doctrine of Fair Use in Patent Law, 100 COLUM. L. REV. 1177 (2000).

<sup>217.</sup> Pub. L. No. 94-553, § 107, 90 Stat. 2541, 2546 (codified as amended at 17 U.S.C. § 107 (2000)). The preamble to section 107 reads:

Notwithstanding the provisions of Section 106, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright.

exception).<sup>218</sup> Part of the reason for this problem is the ad hoc nature of the doctrine, lacking precise definitions in order to remain flexible to adapt to new technologies on a case-by-case basis.<sup>219</sup> It relies on the application of four broad and vague factors to determine whether use is fair.<sup>220</sup> However, the application of these factors has led to inconsistent and unpredictable results. In any given case, for instance, the majority and dissenting opinions may disagree on each factor.<sup>221</sup> It is to be expected that an experimental use exception that resembles the fair use doctrine will cause a tremendous increase in litigation as parties and courts struggle to decide which activities are covered by the exemption in any given case. Accordingly, for this reason alone, the fair use doctrine does not present an efficient model.

It is also interesting to mention that when it comes to copying for educational use, fair use cases mirror two of the experimental use trends presented in this Article. First, when course packets are used for educational purposes, the commercial copy center making the copies for profit is not allowed the fair use defense.<sup>222</sup> This seems to suggest the importance of profit or commercial motive as in the experimental use exception cases. Second, publishers enforcing their copyrights are choosing to sue the commercial copy centers who make the copies rather than the universities who are the direct infringers.<sup>223</sup> Again, this pattern mirrors the de facto practice under the experimental use exception.

## D. Congress Should Expand the Exemption Only for Compelling Reasons

Any expansion of the experimental use exception should occur legislatively and only where necessary.<sup>224</sup> Such legislative pronouncements, in conjunction with subsequent judicial interpretation of legislative intent, offer the best method for addressing any compelling public policy reasons for expansion of the doctrine. To

221. For example, compare Justice O'Connor's majority opinion in Harper & Row, Publishers, Inc. v. Nation Enters., 471 U.S. 539 (1985), with Justice Brennan's dissent.

<sup>218.</sup> A search revealed that since the enactment of the doctrine on October 19, 1976, the courts have decided 823 cases involving fair use claims (search parameters in LEXIS Federal & State Cases, Combined database for "fair use and copyright" after 10/19/76; conducted on 8/2/05). By comparison, during the same time period, only 85 experimental use exception cases were decided (search parameters in LEXIS Federal & State Cases, Combined database for "experimental use exception and not (statutory exemption or prior use defense) and patent infringement" after 10/19/76; conducted on 8/2/05).

<sup>219.</sup> See H.R. REP. NO. 94-1476, at 66 (1976) ("courts must be free to adapt the doctrine to particular situations on a case-by-case basis ...."); see also Iowa State Univ. Research Found., Inc. v. Am. Broad. Cos., 621 F.2d 57, 60 (2d Cir. 1980) ("The doctrine of fair use ... permits courts to avoid rigid application of the copyright statute when, on occasion, it would stifle the very creativity which that law is designed to foster.").

<sup>220.</sup> See 17 U.S.C. § 107 (2000).

<sup>222.</sup> See Princeton Univ. Press v. Mich. Document Servs., 99 F.3d 1381, 1393 (6th Cir. 1996); Basic Books, Inc. v. Kinko's Graphics Corp., 758 F. Supp. 1522, 1530-35 (S.D.N.Y. 1991).

<sup>223.</sup> See id. In Basic Books, Inc. v. Kinko's Graphics Corp., Kinko's paid the publishers \$1,875,000 and was barred from supplying course packets for ten years. Judith Rosen, Kinko's Re-enters Coursepack Market, PUBLISHERS WEEKLY, Sept. 22, 2003, available at http://www.publishersweekly.com/article/CA324109.html? pubdate=9%2F22%2F2003&display=archive.

<sup>224.</sup> See Infigen, Inc. v. Advanced Cell Tech., Inc., 65 F. Supp. 2d 967, 981 (W.D. Wis. 1999) ("[I]t is up to Congress to decide whether there should be an infringement exemption for university-based research laboratories.").

date, Congress has not seen fit, and has indeed refused, to broaden the scope of the experimental use exception to protect universities.<sup>225</sup> As this Article suggests, such congressional refusal may be because the existence and definition of a true problem has not been established.<sup>226</sup>

#### 1. Exemptions to Date

Rather, Congress has acted in specific instances to grant particular exemptions, such as that granted to the pharmaceutical industry in the Hatch-Waxman Act.<sup>227</sup> This process allows Congress to determine whether an endeavor is sufficiently compelling and necessary for the public welfare that it trumps a patent-holder's rights.<sup>228</sup> The provision for generic drugs,<sup>229</sup> medical devices,<sup>230</sup> and drug development in general (as now interpreted by the Supreme Court) has met such criteria. In addition, Congress has also enacted an exemption for infringement of patented medical or surgical procedures.<sup>231</sup> Institutional status—the mere fact that an enterprise is a research university —has not and probably should not fit the bill.

#### 2. A Proposed Standard

Unfortunately, no clear indication of the objective reasons for these exemptions appears to exist; there is no test that would guide the result on the next proposed exemption. Even recognizing that congressional acts are part of a political process, not guided by specific articulable criteria, Congress could benefit, nonetheless, from standards by which to craft legislation on this issue. Further, Congress may also choose to articulate standards that would allow courts to deal with experimental use exception cases.

With that in mind, this Article recommends a test that generally balances the individual patent-holder's rights to exclusivity against society's interests in using her invention. More specifically, in deciding whether to permit infringement and bypass

2007]

<sup>225.</sup> See, e.g., Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, 101st Cong. (1990) (unsuccessful bill proposing exemptions from infringement for university research).

<sup>226.</sup> One legislator noted, "The stated purpose of [the proposed legislation] is to protect university research activity. I fail to understand what universities are being protected from. There has never been a case, to my knowledge, where a university has been sued for patent infringement for carrying on research on a patented invention." H.R. REP. NO. 101-960(I) (1990).

<sup>227.</sup> See 35 U.S.C. § 271(e)(1) (2000); 17 U.S.C. § 906 (2000); 7 U.S.C. § 2544 (2000).

<sup>228.</sup> Congress may also require compulsory licensing in certain areas. See, e.g., Charles Pfizer & Co. v. Fed. Trade Comm'n, 401 F.2d 574, 577 (6th Cir. 1968), cert. denied, 394 U.S. 920 (1969) (holding that the FTC has authority to require compulsory licensing of tetracycline and aueromycin patents on a reasonable royalty basis). In addition, the Clean Air Act provides for compulsory licensing of patents on pollution control devices to those who cannot use substitutes to meet the statutory pollution guidelines. 42 U.S.C. § 7401 et seq. (2000).

<sup>229.</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1603 (codified at 35 U.S.C. § 271(e)).

<sup>230.</sup> See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 664 (1990).

<sup>231.</sup> See 35 U.S.C. § 287(c) (2000).

the patentee's rights, Congress should find that the patent-holder's refusal to license<sup>232</sup> the invention will have an injurious effect on the public welfare *and* on innovation.

To illustrate the test, it may be helpful to revisit the hypothetical posed at the beginning of this Article with Ivan and his Gizmo. Assume that the researchers at the local university believe that Ivan's Gizmo will be useful in finding a cure for cancer. They seek a license from him, but he refuses. In fact, he refuses to license it to anyone.<sup>233</sup> Ivan does not have the knowledge or the resources to use his device the way the university researchers would. The matter is before Congress.<sup>234</sup>

First, Congress should examine whether Ivan's refusal to license could have a potentially injurious effect on the public welfare. Given the importance of finding a cure for cancer, a compelling case for an affirmative response can be made here. Second, Congress should ask if a compelling case can be made that the refusal could have an injurious effect on innovation. Ivan, without the knowledge or resources, cannot use his device to find a cure for cancer (he may not even suspect that it has any connection to cancer). He hinders innovation (i) by not having the ability to research and develop a potentially momentous technology and (ii) by refusing to permit anyone else to invent the technology. Accordingly, this situation would justify Congress curtailing Ivan's rights,<sup>235</sup> and either forcing him to license the technology<sup>236</sup> or declaring that use of the device for research is not an act of infringement where it has been shown that such use would constitute a necessary step of a protocol for finding a cure for cancer.

#### **VI.** CONCLUSION

The *Madey* court's narrow interpretation of the experimental use exception is consistent with precedent, consistent with public policy, and appropriate for university

<sup>232.</sup> Requiring that the prospective infringer seek a license first is in keeping with respect for patent rights. It seems fair that the patent-holder have something akin to a right of first refusal on the patented invention before having Congress decide to curtail or abrogate those rights. This arrangement also permits the marketplace to govern the transaction. *See supra* Part IV.B.

<sup>233.</sup> In reality, Ivan's refusal to license would be highly unusual. He would have so much to gain from participation in finding a cure for cancer through royalties, licensing fees, and possible ownership interests in the cure, that it would make very little sense to refuse. *See supra* Parts IV.B-C. Assuming, however, that he either refuses to license or seeks draconian terms and that there is no other alternative to using his invention, then it is fair for the public, through Congress, to step in.

<sup>234.</sup> Admittedly, Congress (unlike the courts) generally does not deal with an individual situation. However, for purposes of the hypothetical, "Ivan" could represent a corporation or industry practice that has created or is creating the kind of obstacle that would justify congressional intervention.

<sup>235.</sup> This could be seen as a consistent legislative corollary to the policy supporting the defense of patent misuse. Although a patentee's refusal to license does not constitute misuse of the patent, to the extent the behavior has anticompetitive effects on the market, the patent may be held unenforceable. *See generally* ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS § 21.3, at 505-08 (2003).

<sup>236.</sup> This is, in effect, a kind of compulsory licensing. However, unlike other proposed compulsory licensing schemes, this approach is more specific and limited in terms of its scope. For instance, it does not apply to all research tools. *Cf. supra* note 213. Moreover, it requires, as a threshold matter, consideration of the effect on the public welfare and on innovation in the particular circumstances. It also grants the patent-holder an opportunity to negotiate freely with the prospective licensee before facing the blanket imposition of a compulsory license.

research. Given the nature of university research today and its resemblance to industry research, it does not seem fair that universities should receive special treatment from infringement simply by virtue of their being universities. In order to make a patent-holder's right to exclude others meaningful, any attempt to broaden the activities that are exempt from infringement under the doctrine must be done sparingly and only for compelling reasons. Congress should consider expanding the exemption only in situations where a compelling case has been made that a patent-holder's refusal to license threatens the public welfare and innovation.

In practice, *Madey* will probably have very little effect on the way research is conducted at universities. Even if researchers may technically be engaging in patent infringement in their labs (as had become commonplace before *Madey*), they are not likely to suffer repercussions. There are various norms and considerations that greatly favor and protect academic research in a way that will ensure its survival.

Finally, recent gaps have been created in the experimental use exception as a result of the Supreme Court's interpretation of the Hatch-Waxman Act and because of state universities' immunity from patent infringement. Far from leaving the doctrine as an empty shell, however, these gaps weigh in favor of saving and safeguarding the doctrine. The doctrine is still of consequence, for instance, to private universities, individual researchers at state universities, industrial researchers, and the world of nondrug development researchers. Because each chip off the doctrine signals a further erosion of patent-holders' rights and an accompanying harm to the incentives to invent and innovate, careful consideration of the doctrine is still required.