



## IS THE EXPERIMENTAL USE EXEMPTION FOR PATENT INFRINGEMENT STILL NEEDED?

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### ABSTRACT

The judicially created experimental use exemption has traditionally been a limitation on a patent holder's rights because it allows patent infringing activities involving research for mere curiosity or amusement. This exemption was later modified to further protect any research performed by institutions not having a profit motive for the patent infringement, resulting in many institutions freely infringing patented inventions, knowing that broad protection was available under the experimental use exemption. However, in 2002 the Federal Circuit effectively ended the experimental use exemption as a defense for academic institutions, by recognizing that academic institutions can be held liable for infringement for using a patented technology in the course of its own research. Rather than limiting access to these inventions in order to protect patent holders' rights, Congress should impose a compulsory licensing scheme for research tools, which also awards a reasonable royalty to the patent holder for the use of the patented research tool. Mandating compulsory licensing allows access to research tools necessary for progress in science and technology while protecting the patent holder's rights in the patented research tool.

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## IS THE EXPERIMENTAL USE EXEMPTION FOR PATENT INFRINGEMENT STILL NEEDED?

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### INTRODUCTION

The United States Constitution authorizes Congress to award temporary and exclusive property rights to anyone who creates a useful invention.<sup>1</sup> Congress enacted the present version of patent law in the Patent Act of 1952,<sup>2</sup> which gives a patent holder the right to exclude others from making, using, selling, offering to sell, or importing a patented invention in the United States.<sup>3</sup> Anyone who violates a patent holder's exclusive rights within the United States, and without the permission of the patent holder, statutorily infringes the patent.<sup>4</sup> A defendant need only commit a single act in violation of one of the listed activities to be held liable for patent infringement.<sup>5</sup>

The judicially created experimental use exemption (considered both an exception and defense to patent infringement) is a limitation on a patent holder's exclusive rights.<sup>6</sup> The experimental use exemption arose out of dicta in which Justice Joseph Story, a leading intellectual property judge in the early years of American patent litigation, held a defendant not liable for patent infringement.<sup>7</sup> In explaining his decision, Justice Story stated Congress did not intend for the law to punish someone who made or used a patented invention out of curiosity, or for mere amusement.<sup>8</sup> In subsequent cases, the experimental use exemption was modified to include patent infringers who have no profit motive for infringing the patent.<sup>9</sup> This exemption was further modified to expressly exclude patent infringers whose infringing activities are within the infringer's line of business.<sup>10</sup> While the Federal Circuit has repeatedly deemed the experimental use exemption "truly narrow," not until recently did the court deny this defense in a lawsuit of patent infringement committed by a university.<sup>11</sup>

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<sup>1</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>2</sup> Ch. 950, 66 Stat. 792 (codified as Title 35 of the U.S.C. (2000)).

<sup>3</sup> 35 U.S.C. §§ 154, 271(a) (2002). The 1996 amendment added *offering for sale* and *importing* to the rights of *making*, *using* and *selling*. *Id.*

<sup>4</sup> 35 U.S.C. § 271 (2000).

<sup>5</sup> *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964); *Coakwell v. U.S.*, 372 F.2d 508, 510 (Ct. Cl. 1967).

<sup>6</sup> 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>7</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>8</sup> *Id.* at 1121.

<sup>9</sup> *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

<sup>10</sup> *Cimiotti Unhairing Co. v. Derboklow*, 87 F. 997 (C.C.E.D.N.Y. 1898).

<sup>11</sup> *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003).

In the wake of the *Madey v. Duke University* decision, both scientists and legal experts have voiced opinions about the boundaries of a patent holder's rights and how those rights may be protected without unnecessarily restricting basic research. The debate is especially strong regarding patented tools used in biomedical research that directly benefits the public.<sup>12</sup>

This article describes the evolution of the experimental use exemption from its origin to its present form. Next, the article examines federal legislation that has allowed academic institutions tremendous capitalization on research, by allowing researchers to patent inventions that were funded by federal grant money. Such legislation dramatically increased the number of patents issued to academic institutions, and it subsequently increased joint commercial ventures between academic and industrial science. This article addresses the changing relationship of academic and industrial science and its impact on the need for an experimental use exemption. Finally, this article outlines some possible strategies Congress may employ for maintaining a "truly narrow" experimental use exemption without eviscerating the property rights of patent holders.

## I. EVOLUTION OF THE EXPERIMENTAL USE EXEMPTION

The judicially created experimental use exemption (considered both an exception and defense to patent infringement) is a limitation on a patent holder's right to exclude others from making, using, selling, offering to sell, or importing the invention into the United States.<sup>13</sup> The experimental use defense to patent infringement originated in an 1813 case in which the defendant was found not guilty of infringing a patent for a card-making machine.<sup>14</sup> Explaining his decision in dicta, Justice Joseph Story stated that the intent of the patent laws was not to punish a man who infringes a patent "merely for philosophical experiments" or for purposes of making an invention in order to verify its functionality.<sup>15</sup>

In a subsequent case, *Sawin v. Guild*, Justice Story applied the experimental use defense to exempt alleged patent infringers who had no intention of infringing the patent in order to make a profit.<sup>16</sup> Justice Story rationalized 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>17</sup> Furthermore, 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>18</sup> This holding modified the experimental use exemption and established the motive of profit as the key to whether a particular alleged infringing activity falls under the experimental use exemption.<sup>19</sup>

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<sup>12</sup> Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 961, 1018–19 (Feb. 14, 2003).

<sup>13</sup> Mueller, *supra* note 6, at 19.

<sup>14</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>15</sup> *Id.* at 1121.

<sup>16</sup> 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

<sup>17</sup> *Id.* at 555.

<sup>18</sup> *Id.*

<sup>19</sup> Mueller, *supra* note 6, at 20.

Nearly fifty years later, Judge Shipman outlined the present test for experimental use of a patented invention.<sup>20</sup> Judge Shipman held that courts have accepted the defense to patent infringement when the alleged infringing activity is “for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement....”<sup>21</sup> This test established the present-day, “truly narrow” experimental use exemption that has only been used successfully for patent infringers whose activities were motivated not by financial gain, but only by amusement or verification of the workings of the invention.

The first case involving the experimental use exemption and its role in academic research came in 1935 with *Ruth v. Stearns-Roger Mfg. Co.*<sup>22</sup> In *Ruth*, the defendant illegally sold parts for a patented flotation device to several customers, including the Colorado School of Mines.<sup>23</sup> These parts allowed the customers to utilize the improved device without purchasing an entirely new instrument.<sup>24</sup> The district court held the defendant liable for contributory patent infringement but exempted the sales to the Colorado School of Mines because the school used its instruments in conducting research.<sup>25</sup> Thus, the school’s research activities fell within the experimental use exemption because the school derived no financial gain from the use of the patented invention.<sup>26</sup>

Academic institutions believed the *Ruth* decision provided a broad umbrella of protection from patent infringement for any educational research. Most academic institutions freely infringed patented inventions until 2002, when the Federal Circuit weighed in on the experimental use exemption as it relates to academic research.<sup>27</sup> The court in *Madey* found Duke University liable for patent infringement when Duke continued to use Madey’s patented laser after Madey himself left the university. Previously, the district court held that Duke University researchers were using the patented laser for basic scientific research that was not aimed at commercial ventures and therefore fell under the experimental use exemption.<sup>28</sup> However, the Federal Circuit overturned the district court’s decision and held that Duke’s own patent policies verified the use of the laser as furthering its “legitimate business objectives.”<sup>29</sup> The Federal Circuit chastised the district court for its broad interpretation of the experimental use exemption to apply to any research for academic, experimental, or non-profit purposes.<sup>30</sup> The Federal Circuit stated that the focus should not be on whether Duke is a non-profit institution, since such academic institutions frequently conduct research with little or no commercial value.<sup>31</sup> Instead, the focus should be on Duke’s “legitimate business objectives, including educating and enlightening students and faculty,” and the university’s research

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<sup>20</sup> *Poppenhusen v. Falke*, 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279).

<sup>21</sup> *Id.* at 1049.

<sup>22</sup> 13 F. Supp. 697 (D. Colo. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936).

<sup>23</sup> *Id.* at 699.

<sup>24</sup> *Id.* at 710.

<sup>25</sup> *Id.* at 703.

<sup>26</sup> *Id.* at 713.

<sup>27</sup> *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003).

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

<sup>29</sup> *Madey*, 307 F.3d at 1361.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 1362.

which “increase[s] the status of the institution and lure[s] lucrative research grants, students and faculty.”<sup>32</sup> The Federal Circuit characterized Duke as a business and all research done at the university as being in Duke’s line of business, thereby removing the research (and any patent infringement that occurs in the research) from the experimental use exemption.<sup>33</sup>

The Federal Circuit cited Duke’s own policies regarding the patenting of research conducted at the university as being part of its business objective.<sup>34</sup> The Federal Circuit said Duke “is not shy” about attaining licenses for its patented work, and such licensing revenue contributes to Duke’s “legitimate business.”<sup>35</sup> While not expressly stating so, the Federal Circuit implied that the university’s *intent* in using the laser was to profit in the future. Indeed, the Federal Circuit noted 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 the fact that Duke had already established an hourly fee for any non-academic laser users (although such fees had not yet been charged to those users).<sup>36</sup>

The *Madey* decision effectively ended the experimental use exemption as a defense for patent infringement by academic institutions.<sup>37</sup> In order to understand the court’s rationale, we must examine how academic research has taken on business characteristics as a result of federal legislation.

## II. THE COURTSHIP OF ACADEMIC AND INDUSTRIAL SCIENCE

In 1980, Congress passed the Bayh-Dole University and Small Business Patent Procedures Act, which allows private ownership of patented inventions from research funded by the federal government.<sup>38</sup> Its purpose was to accelerate the development of inventions that would benefit the public by allowing universities, small businesses and nonprofit institutions to hold patents on the inventions they generated with public money.<sup>39</sup> While the federal government retained some rights to the inventions,<sup>40</sup> it parceled away most of its property rights to the research labs.

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<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 1363 n.7.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 1356 n.5.

<sup>37</sup> See Eisenberg, *supra* note 12, at 1019.

<sup>38</sup> Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019–28 (codified at 35 U.S.C. §§ 200–12 (2000)).

<sup>39</sup> 35 U.S.C. § 200 (2000).

<sup>40</sup> 35 U.S.C. § 202(c)(4) (2002) (“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 . . .”).

[T]he Federal agency . . . shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such – (1) action is necessary . . . to achieve practical application of the subject invention; (2) . . . to

Historically, the federal government owned all rights to research sponsored by federal funds, and such research typically was not patented because it was considered “public research.”<sup>41</sup> As such, “public research” was immediately and freely available to the public, whereas “commercial research” funded by private investment was kept secret until it was patented and able to generate revenue by license.<sup>42</sup> However, progress in high-tech research, especially biomedical and electronics-related research, increased investment in private industry, which in turn increased interest in developing basic research.<sup>43</sup>

In passing the Bayh-Dole Act, Congress recognized that the collaboration between scientific research and business would allow rapid and efficient commercial development of basic research.<sup>44</sup> Congress further recognized that allowing academic institutions to pursue commercial development of their federally funded research would be of greater value to the public than immediately distributing that research to the public.<sup>45</sup>

The experimental use exemption was originally thought to be unaffected by the Bayh-Dole Act. Traditionally, industrial science refrained from pursuing litigation against academic infringers due to the risk of bad publicity, high litigation costs, and the risk of having patents deemed partially or wholly invalid.<sup>46</sup> A turning point came when the experimental use defense failed in litigation between two industrial giants in the landmark case *Roche Products, Inc. v Bolar Pharmaceutical Co.*<sup>47</sup>

In *Roche*, the Federal Circuit reversed the lower court’s decision and held Bolar liable for patent infringement.<sup>48</sup> Bolar used Roche’s patented drug-testing components to develop a generic version of a drug.<sup>49</sup> While Bolar planned to delay manufacturing the generic drug until Roche’s patent expired, Bolar needed to begin the drug testing process in order to get approval from the Food and Drug Administration (“FDA”), a process that could take several years.<sup>50</sup> Bolar maintained its testing was purely experimental, but the Federal Circuit found otherwise.<sup>51</sup>

In handing down its decision in *Roche*, the Federal Circuit stated that Bolar’s use of the patented drug for testing violated the plain meaning of “use” in the patent

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alleviate health or safety needs . . . (3) to meet requirements for public use specified by Federal regulations . . . or (4) . . . because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204 [which requires substantial manufacture of the invention in the United States].

35 U.S.C. § 203 (2002). See generally 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 (2000).

<sup>41</sup> Valoir, *supra* note 40, at 212–13.

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

<sup>43</sup> See *id.*

<sup>44</sup> Valoir, *supra* note 40, at 213.

<sup>45</sup> *Id.*

<sup>46</sup> John Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 961, 1021 (Feb. 14, 2003).

<sup>47</sup> 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

<sup>48</sup> *Id.* at 860–61.

<sup>49</sup> *Id.* at 860.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 858.

infringement laws.<sup>52</sup> The Federal Circuit pointed out that an infringement suit may be brought any time an unauthorized party uses a patented invention, with no legal requirement for the patent holder to suffer damage or lost sales because of the infringement.<sup>53</sup> Thus, even though Bolar's activities caused no financial loss to Roche because the generic drug was not yet on the market, the Federal Circuit refused to allow the drug testing under the experimental use exemption because Bolar *intended* to profit in the future.<sup>54</sup>

At first glance this decision may seem contrary to the well-developed theories of the experimental use exemption, which require a showing that the infringing activity resulted in economic gain by the infringer.<sup>55</sup> However, the Federal Circuit focused instead on Bolar's ultimate profit motive, which was impetus in using the patented drug for testing. The Federal Circuit stated that Bolar's drug testing activity fell outside of the "truly narrow" experimental use exemption because it was conducted in Bolar's ordinary course of business.<sup>56</sup> The court said it would not allow infringing activities to be masked as experimental use when such activities have "definite, cognizable, and not insubstantial commercial purposes."<sup>57</sup>

The Federal Circuit cited several Court of Claims cases in support of its restrictive application of the experimental use exemption, and concluded that none of the cases allowed infringing activities that contributed to the infringers' business interests.<sup>58</sup> This decision further modified the experimental use exemption and firmly established that the intent to make a profit is implied if the allegedly infringing activity is associated with the infringer's legitimate business interests.

In response to the Federal Circuit's decision in *Roche*, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.<sup>59</sup> In addition to lengthening the patent term for drugs requiring FDA approval before entering the market, the Hatch-Waxman Act also exempts certain activities that would otherwise be infringing.<sup>60</sup> The provisions of the Act balance each other. The original patent holder is given an extension to the patent term since several years of the patent's original term were lost during the FDA approval process. In trade, generic drug manufacturers are allowed to use the original patented drug, although it is still protected by the patent, so the generic drug can complete the FDA approval process and be ready for market release as soon as the original patent expires. The Act states 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 regulates drug manufacture, use, or sale, is not an act of patent infringement.<sup>61</sup> Under this federal legislation, generic

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<sup>52</sup> *Id.* at 863.

<sup>53</sup> *Id.* at 861.

<sup>54</sup> *Id.* at 863.

<sup>55</sup> *E.g.*, *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813)(No. 17,600); *Poppenhusen v. Falke*, 19 Cas. 1048 (C.C.S.N.Y. 1861); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935).

<sup>56</sup> *Roche*, 733 F.2d at 863.

<sup>57</sup> *Id.* at 864.

<sup>58</sup> *Id.* at 863.

<sup>59</sup> Mueller, *supra* note 6, at 25.

<sup>60</sup> 35 U.S.C. §§ 156, 271 (2002).

<sup>61</sup> 35 U.S.C. § 271(e) (2002).



drug companies are permitted to freely use patented drugs and drug components in order to test and gather data for FDA approval, before the patent expires.<sup>62</sup>

Five years after Congress passed the Hatch-Waxman Act, the United States Supreme Court interpreted the act to include testing for medical devices, which also undergo a lengthy FDA approval process.<sup>63</sup> The Court held that Congress intended to provide symmetry in the legislation since both drug and medical device patent terms were extended under §§ 201 and 202, allowing patent holders to recover some of the exclusivity time spent while seeking FDA approval.<sup>64</sup> Likewise, patent holders of both drug and medical device patents must tolerate the infringing activities of competing companies who conduct FDA approval tests prior to the expiration of the patent terms.<sup>65</sup>

Several years later, in 2000, the Federal Circuit reiterated its interpretation of the experimental use exemption following the Hatch-Waxman Act in its decision in *Embrex, Inc. v. Service Engineering Corp.*<sup>66</sup> The Plaintiff, Embrex, was the exclusive licensee of a patent for vaccinating chicks before they hatched.<sup>67</sup> Service Engineering retained scientists to design a similar machine that would not infringe Embrex's patent.<sup>68</sup> When Embrex filed suit for patent infringement, Service Engineering defended itself by claiming its activities were merely involved in testing its own machine.<sup>69</sup> The Federal Circuit found these tests were conducted "expressly for commercial purposes," and refused to apply the "very narrow" experimental use exemption.<sup>70</sup> The court held Service Engineering liable for patent infringement.<sup>71</sup> Furthermore, the court reiterated that the experimental use exemption 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>72</sup>

The limits of the "guise of scientific inquiry" remained undetermined until the court spoke again in *Madey*.<sup>73</sup> *Madey* narrowed the experimental use exemption almost into oblivion. 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. While the court did not eliminate the experimental use exemption, the court did render the exception worthless to academic institutions.<sup>74</sup>

In discussing the District Court's holding, the Federal Circuit addressed the growing involvement of academic institutions with commercial enterprises and recognized that most academic institutions have extensive policies regarding

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<sup>62</sup> Donald S. Chisum, CHISUM ON PATENTS, § 16.03 [1] (2003).

<sup>63</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990).

<sup>64</sup> *Id.* at 670–73.

<sup>65</sup> *Id.*

<sup>66</sup> 216 F.3d 1343 (Fed. Cir. 2000).

<sup>67</sup> *Id.* at 1346.

<sup>68</sup> *Id.* at 1346–47.

<sup>69</sup> *Id.* at 1349.

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

<sup>71</sup> *Id.* at 1351.

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

<sup>73</sup> *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

<sup>74</sup> Eisenberg, *supra* note 12, at 1019.

patenting the work of their own researchers.<sup>75</sup> More importantly, the Federal Circuit stated that the district court misinterpreted the experimental use exemption in *Ruth*, an academic case relied on by most university legal departments.<sup>76</sup> Without expressly overturning *Ruth*, the Federal Circuit stated that the district court failed to analyze the “character, nature and effect” of the school’s infringing activities and instead determined that the experimental use exemption applied because the school itself was non-profit.<sup>77</sup> The court said such broad application of the experimental use exemption is inconsistent with its intended “very narrow” purpose.<sup>78</sup>

The Federal Circuit’s identification of Duke University as a legitimate business has ignited controversy throughout the scientific community.<sup>79</sup> Prior to *Madey*, universities that relied on the district court’s interpretation of the experimental use exemption in *Ruth* had not considered the use of patented technologies by academic research to be an infringing activity. However, following *Madey*, universities are rethinking that position.<sup>80</sup> Some academics have cried foul, arguing that the court’s decision will hinder research by forcing scientists to spend precious research time and money to obtain permission from patent holders, in addition to further time and money spent along the way to keep track of which patented technologies are being used in their research.<sup>81</sup> Still, academics recognize the line between basic and commercial research at universities is blurred due to increasing industry-academic research collaboration.<sup>82</sup> These academics argue that the court is finally holding universities accountable for their commercial research activities and that universities should no longer be allowed to blatantly infringe the patents of others while seeking and enforcing their own.<sup>83</sup>

Voices from industry have been noticeably silent, but in a recent survey of academic and industrial scientists, most scientists from both camps admitted they tolerate patent infringement by universities because litigation is too costly, the risk of bad publicity is too great, or the risk of the court holding their patents narrowed or invalidated is high.<sup>84</sup> Some scientists even admitted 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>85</sup> This idea is based on scientists’ own admission 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 would then be forced

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<sup>75</sup> *Madey*, 307 F.3d at 1355.

<sup>76</sup> *Id.* at 1362.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 1361–62.

<sup>79</sup> See David Malakoff, *Universities Ask Supreme Court to Reverse Patent Ruling*, 299 SCIENCE 1, 26–27 (2003); David Resnik, *Letter to the Editor: Patents and the Research Exemption*, 229 SCIENCE 765, 821–22 (2003); Eliot Marshall, *The UPSIDE of Good Behavior: Make Your Data Freely Available*, 229 SCIENCE 961, 990 (2003).

<sup>80</sup> Malakoff, *supra* note 79, at 26; Resnik, *supra* note 79, at 821.

<sup>81</sup> Malakoff, *supra* note 79, at 26.

<sup>82</sup> Resnik, *supra* note 79, at 821.

<sup>83</sup> *Id.*

<sup>84</sup> Walsh, *supra* note 46, at 1021.

<sup>85</sup> *Id.*

to obtain a license for the technologies they have used in their research methods, or search for new methods to solve the problems.

With impeccable timing, the National Academy of Sciences (“Academy”), which has no legal authority but retains great influence over particular scientific journals, issued a decree in early 2003 strongly urging scientists to release published materials to other scientists as soon as possible, especially high-tech information such as molecular biological material and computer software source codes.<sup>86</sup> The Academy previously appointed a review panel to study the issue of data release in light of the “concerns about increasing commercial ties in academic life,” but many scientists cite the fervor surrounding sequencing the human genome two years ago.<sup>87</sup> Celera Genomics, one of the key companies in charge of the sequencing project, refused to release the data to a public database and instead charged users for viewing the data on its own Web site. Turmoil ensued because Celera charged different access fees to academic and commercial users.<sup>88</sup>

In the wake of this controversy, the Academy’s decree states that any scientist who wants to “verify or replicate” a published claim by another should have easy access to all necessary materials—including materials protected by patent.<sup>89</sup> At the same time, the Academy’s report indicates that licensing of such materials to those who request them is acceptable.<sup>90</sup> However, the report urges patent holders to issue equal license fees to everyone, regardless of whether the request comes from academia or industry since “[t]here is no clear line between ‘for-profit sector’ and ‘academic’ research.”<sup>91</sup> While it is too early to tell if the scientific community will abide by its own policing, questions regarding enforceability of such a decree have already surfaced.<sup>92</sup>

Another twist in the plot has been infringement by state universities. In 1992, Congress passed legislation that expressly abrogated sovereign immunity under the Eleventh Amendment for states, instrumentalities of states, and state employees acting in their official capacity in regard to patent infringement.<sup>93</sup> However, in 1999 the Supreme Court deemed the law unconstitutional in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*.<sup>94</sup> In striking down the law, the Court said state sovereign immunity can only be abrogated under the Fourteenth Amendment, not under Congress’ Article I powers.<sup>95</sup> Since Congress did not give a basis for abrogation of state immunity from patent infringement

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<sup>86</sup> NAT’L. ACAD. SCI., *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*, available at <http://books.nap.edu/books/0309088593/html/> (March 4, 2003) [hereinafter NAT’L. ACAD. SCI.].

<sup>87</sup> Marshall, *supra* note 79.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> NAT’L. ACAD. SCI., *supra* note 86 (noting that the Massachusetts Institute of Technology’s (MIT) patented process for small interfering RNAs (siRNAs) can be licensed directly from MIT or indirectly through purchase of RNA oligonucleotides from a licensed vendor, since MIT incorporated a license for the process of making siRNAs in its commercially available product).

<sup>91</sup> *Id.*

<sup>92</sup> Marshall, *supra* note 79.

<sup>93</sup> Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, § 2(a)(2), 106 Stat. 4230 (1992) (codified at 35 U.S.C. § 296 (2000)).

<sup>94</sup> 527 U.S. 627, 647–48 (1999).

<sup>95</sup> *Id.* at 637.

liability under the Fourteenth Amendment, the law was unconstitutional.<sup>96</sup> However, the decision in *College Savings Bank* does not leave patent holders without redress against state universities that infringe patents.

Under the *Ex parte Young* doctrine, state workers may be sued in federal court in their individual capacity.<sup>97</sup> Further, although patent holders cannot obtain monetary compensation from the state, they may obtain injunctive relief.<sup>98</sup> However, injunctive relief against a state university under Eleventh Amendment state immunity would still make litigation expensive and time-consuming.<sup>99</sup>

The ramifications of *College Savings Bank* have not yet been explored in litigation but the decision leaves open the potential for diverting scientific research money away from private industry and towards collaborating academic institutions.<sup>100</sup> As discussed, collaborations between private industry and academic research labs have grown tremendously since the passage of the Bayh-Dole Act.<sup>101</sup> However, 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>102</sup> It is not known what the threshold is for a minimum level of state funding or control that enables the research endeavor to be an instrumentality of the state, rather than a disguised extension of the private industry collaborator.<sup>103</sup>

### III. FEDERAL LEGISLATION REGARDING THE EXPERIMENTAL USE EXEMPTION

This article proposes development of federal legislation that increases access to inventions that further science and technology while preserving the patent holder's property rights. Private industry would likely oppose a statutory experimental use exemption that would give competing universities free rein to use inventions developed by private industry.<sup>104</sup> Furthermore, an overly broad experimental use exemption would effectively strip the patent holders of their basic property rights, which would reduce incentives for scientific innovation.<sup>105</sup> Congress must formulate an experimental use exemption neither too narrow, nor too broad, but instead one that represents a compromise between protecting patent holders' property rights and allowing necessary access to scientific inventions that are used to further scientific and technological development.

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<sup>96</sup> *Id.* at 639–43.

<sup>97</sup> *Ex parte Young*, 209 U.S. 123, 154 (1908); see also Peter S. Menell, *Symposium on New Directions in Federalism: Economic Implications of State Sovereign Immunity from Infringement of Federal Intellectual Property Rights*, 33 LOY. L.A. L. REV. 1399 (2000).

<sup>98</sup> Menell, *supra* note 97, at 1404.

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

<sup>100</sup> Sharon K. Sandeen, *Preserving the Public Trust in State-Owned Intellectual Property: A Recommendation for Legislative Action*, 32 MCGEORGE L. REV. 385 (Winter 2001); see also Mueller, *supra* note 6, at 14.

<sup>101</sup> Valoir, *supra* note 40, at 234.

<sup>102</sup> Mueller, *supra* note 6, at 33–34.

<sup>103</sup> See *id.* at 36.

<sup>104</sup> Resnik, *supra* note 79.

<sup>105</sup> Mueller, *supra* note 6, at 41.

One possible solution is compulsory licensing. Proposed licensing agreements range from narrow reach-through licensing of patented research tools<sup>106</sup> to broad research exemptions for patented work such as DNA sequences.<sup>107</sup> Reach-through licensing implements a royalty fee schedule based on the ultimate market value of the future product generated by using the research tool, rather than the present market value of the tool itself.<sup>108</sup> Such licensing agreements are especially attractive to small companies that can access the research tool with little or no upfront costs, along with a promise to pay royalties from any future product that results from use of the tool.<sup>109</sup> Reach-through licensing has been opposed by the National Institutes of Health (“NIH”), however, due to the restrictions it imposes on future products undetermined at the time of the licensing agreement.<sup>110</sup> The NIH has stated that such commercial attachments to future inventions complicate the problem of ensuring easy access to the invention by all scientists.<sup>111</sup> Nonetheless, reach-through licensing is presently employed frequently, especially in the areas of biotechnology and pharmaceutical research.<sup>112</sup>

Under NIH guidelines, research tools encompass any tool a scientist may use in a laboratory in order to procure a “down-stream” invention.<sup>113</sup> NIH has defined research tools to include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, DNA clones and cloning tools, methods, equipment and machines.<sup>114</sup> The NIH guidelines were proposed in response to concern that scientists were denied access to research tools when inventors would refuse to transfer or license the technologies.<sup>115</sup> While the NIH supports seeking patents on inventions and licensing the inventions to scientists, the institute strongly opposes “reach-through” licensing as a solution to the access problem.<sup>116</sup> Instead, the NIH supports non-exclusive licensing in the form of “execution or annual fees.”<sup>117</sup> The NIH also recommends establishing different licenses for experimentation done *with* the research tool, rather than *on* the research tool.<sup>118</sup> Research done *with* the research tool would include developing or preparing a final marketable product that may or may not incorporate the research tool used, while research *on* the tool would involve only manipulating the tool itself in order to improve it or further define its character.<sup>119</sup>

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<sup>106</sup> *Id.* at 58–65.

<sup>107</sup> Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1679 (Dec. 2001).

<sup>108</sup> Mueller, *supra* note 6, at 58.

<sup>109</sup> Thomas J. Kowalski & Christian M. Smolizza, *Reach-through licensing: A U.S. perspective*, PHARMALICENSING (Jul. 14, 2000), available at [http://pharmalicensing.com/features/disp/963567614\\_396edffell132c5](http://pharmalicensing.com/features/disp/963567614_396edffell132c5).

<sup>110</sup> 64 Fed. Reg. 72090, 72091 (Dec. 23, 1999).

<sup>111</sup> *Id.*

<sup>112</sup> Kowalski, *supra* note 109.

<sup>113</sup> 64 Fed. Reg. 72090, 72090–92 (Dec. 23, 1999).

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

<sup>115</sup> *Id.*

<sup>116</sup> Mueller, *supra* note 6.

<sup>117</sup> 64 Fed. Reg. 72090 (Dec. 23, 1999).

<sup>118</sup> *Id.* at 72093.

<sup>119</sup> *Id.*

Compulsory licensing has been opposed on the basis that it would encourage inventors to keep their inventions hidden and not seek patent protection for fear of being forced to license it.<sup>120</sup> For the inventor with a break-through invention, keeping the invention secret would allow the patent to retain more value than if it were patented and forced into the hands of competitors through compulsory licensing. However, keeping inventions secret runs contrary to the purpose of the patent law, which is to promote science and reveal inventions to the public.<sup>121</sup>

Furthermore, in the past, academic research was conducted as a race to publish information. Today, however, the “race to publish” has been replaced with a “race to patent” due to the involvement of academic institutions in patenting and commercially developing their inventions. Taken in the context of the National Academy of Sciences’ recent decree asking scientists to withhold from publication any data that they do not intend to share with the larger scientific community, the possibility of scientists maintaining their inventions in secret is greater than ever, regardless of compulsory licensing.

However, those in favor of compulsory licensing point to foreign patent policies, as well as to the doctrine of fair use under the United States Copyright law which grants freedom to use copyrighted materials to anyone for research or education.<sup>122</sup> Indeed, Japanese patent law provides for a limitation on the patent holder’s rights “for the purposes of experiment or research.”<sup>123</sup> Likewise, France, Germany and Great Britain all have patent laws that exempt certain activities, which would otherwise be infringing for experimental or non-commercial purposes.<sup>124</sup> Proponents of implementing a compulsory licensing scheme in the United States argue that such a scheme has not diminished scientific innovation whatsoever in Europe and Japan, and may, in fact, contribute to innovation by increasing access to patented inventions.<sup>125</sup>

Another argument offered in favor of compulsory licensing is that it may be a remedy in litigation for patent infringement. The courts have used this remedy sparsely however, usually only after a showing of egregious acts such as fraudulently obtaining the patent, pursuing litigation as a mere sham, or violating antitrust laws.<sup>126</sup>

In the past, several bills introduced to Congress mandating compulsory licensing for pharmaceutical drugs have faced stiff opposition from both patent holders as well as patent practitioners.<sup>127</sup> Pharmaceutical drug companies maintained that compulsory licensing would thwart drug development, since research and development of drugs is time-consuming and expensive, and without the incentive of

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<sup>120</sup> Joseph Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275, 1291 (2001).

<sup>121</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>122</sup> Mueller, *supra* note 6, at 37–41.

<sup>123</sup> Japanese Patent Law of 1959, as amended through May 6, 1998.

<sup>124</sup> Mueller, *supra* note 6, at 37–41.

<sup>125</sup> Gitter, *supra* note 107, at 1682–86.

<sup>126</sup> Yosick, *supra* note 120, at 1281–82 (commenting on patent infringement case of *In re Indep. Serv. Org. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000)).

<sup>127</sup> *Id.* (commenting on the *Hart Bill* of 1973, and the *Affordable Prescription Drugs Act* of 1999); see also Christopher K. Eppich, *Patenting Dilemma: Drugs For Profit Versus Drugs For Health*, 43 SANTA CLARA L. REV. 289, 291 (2002).

exclusive patent protection, investors will stop investing in drug companies.<sup>128</sup> These bills, however, involved compulsory licensing of end-product pharmaceutical drug inventions where the primary consumer is not a research scientist, but instead is a member of the public acting through a physician or pharmacist.<sup>129</sup> The compulsory license scheme this article proposes for using research tools would not apply to such end-product inventions as pharmaceutical drugs.<sup>130</sup>

Clearly, members of the scientific community, as well as the legal community, recognize the need for legislative action in deciding the role that patented inventions will play in the joint efforts of academic and industrial research. While it is important to maintain dissemination of technology to the public, it is equally important to protect the property rights of patent holders.

This article proposes to retain the “truly narrow” experimental use exemption while imposing a compulsory licensing scheme for research tools. In keeping with Justice Story’s original conclusion, and echoing a part of a proposal first put forth by Professor Rebecca Eisenberg,<sup>131</sup> any non-commercial use of a patented invention to verify the invention functions as described or fulfils its proposed utility should be exempt from infringement liability.<sup>132</sup>

Beyond this, Congress should mandate a compulsory licensing scheme that would award a reasonable royalty to the patent holder for use of research tools. For the purposes of compulsory licensing, Congress should adapt the NIH definition of research tools with one further limitation: the research tool itself is not incorporated into the end product.<sup>133</sup> Mandating compulsory licensing for the use of patented research tools would allow scientists access to necessary inventions used to further scientific development, while protecting the patent holder’s economic interests in the commercial development of marketable products that benefit the public.<sup>134</sup>

The proposed exemption would only apply to the *use* element of patent infringement, leaving the patent holder the option of authorizing a licensee to make the invention.<sup>135</sup> Research tools inherently provide the basis for much of the conflict regarding the experimental use exemption, since the value of the invention is determined by its use.<sup>136</sup> End products, however, are inventions generated by using research tools (such as diagnostic tests or pharmaceutical drugs) whose value is predetermined by the character of the invention itself.<sup>137</sup>

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<sup>128</sup> Yosick, *supra* note 120, at 1291–92.

<sup>129</sup> 64 Fed. Reg. 72090, 72094–96 (Dec. 23, 1999).

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

<sup>131</sup> Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074–78 (1989).

<sup>132</sup> *Id.* Such exemption has been proposed as part of a 3-prong exemption model by Eisenberg: 1. Exempt activities that verify the invention is enabled as described, 2. Do not exempt research conducted with the research tool in order to generate a down-stream product, 3. Mandate compulsory licensing for research conducted on the tool for improving the tool or “designing around” it. *Id.* Such a compulsory license would ordinarily be applied once the infringing activity has already occurred.

<sup>133</sup> Thus, the proposed licensing would not involve the infringement element of *sell*, since the licensee would generate a new product which, in its final stage, physically lacks the research tool.

<sup>134</sup> Gitter, *supra* note 107, at 1681–85.

<sup>135</sup> See 35 U.S.C. § 271(a)(2000).

<sup>136</sup> Kowalski, *supra* note 109.

<sup>137</sup> *Id.* see also 64 Fed. Reg. 72090 (Dec. 23, 1999).

Calculating a “reasonable royalty” can be done in a number of ways, based on existing contractual licensing agreements, as well as case law involving infringement suits. One alternative is for manufacturers of research tools to include an inherent license when others buy the product—this increases the cost of the product but preserves the patent holder’s rights.<sup>138</sup> Another alternative is to calculate the licensing fee as a percentage of the infringer’s “net margin” of its operating income.<sup>139</sup> Yet another option is to base the licensing royalty on the difference between the infringer’s “normal net profit” and the “anticipated net profit” the infringer will ultimately realize as a result of infringing activities.<sup>140</sup> Clearly, establishing a “reasonable royalty” may not be a simple task but one that is necessary to ensure fair dealing both among and between scientists in academic and industrial settings. One inherent safeguard against inflated royalty fees under the proposed compulsory licensing program is that academic and industrial scientists would be cross-licensing their technologies to each other.

As discussed, academic research cannot easily be distinguished from industrial research.<sup>141</sup> The Bayh-Dole Act allowed for heavy commercialization of federally funded inventions, which caused a massive entanglement of industry and academic research.<sup>142</sup> Industrial science is now able to build on basic research started in academic institutions, and academic institutions are now pursuing commercial applications of their inventions, as well as starting related biotech companies of their own.<sup>143</sup> Thus, in accordance with the National Academy of Sciences’ decree, compulsory licensing of research tools should apply regardless of whether the patent holder is in private industry or an academic setting.

Applying the proposed compulsory licensing scheme evenhandedly to patent holders from academic and private industry alike will lessen the impact of potential shifting of resources from industry to state institutions following the decision in *College Savings Bank*. While state institutions will maintain their Eleventh Amendment sovereign immunity from patent infringement liability, such institutions would still be required to license patented research tools under the proposed compulsory licensing scheme. Such an application of the proposed compulsory licensing scheme recognizes that state universities have business objectives in mind

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<sup>138</sup> NAT’L. ACAD. SCI., *supra* note 86.

<sup>139</sup> John McMullen & David Halprin, *A New Technique for Quantifying Reasonable Royalty from Appropriate Case Law*, 75 J. PAT. & TRADEMARK OFF. SOC’Y 843, 844 (1993) (stating such license fee “gives a relative, but quantitative, measure of the importance of the infringing activity to the infringer’s financial performance”).

<sup>140</sup> Richard Toikka, *Patent Licensing Under Competitive and Non-Competitive Conditions*, 82 J. PAT. & TRADEMARK OFF. SOC’Y 279, 280 (2000).

<sup>141</sup> NAT’L. ACAD. SCI., *supra* note 86.

<sup>142</sup> Resnik, *supra* note 79.

<sup>143</sup> Jeff Gerth & Sheryl Gay Stolberg, *Medical Merchants: Birth of a Blockbuster: Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, Apr. 23, 2000, at Section 1; Joe Alper, *Biotech Thinking Comes to Academic Medical Centers*, 299 SCIENCE 1265, 1303 (Feb. 28, 2003). Alper describes a “not-for-profit biotech” start-up company doing business under The Harvard Medical School. *Id.* The company’s founders say the business objective is to maintain research and address patient needs along with pursuing drug development without focusing on profitability. *Id.* Harvard Medical School acknowledged the start-up biotech company was in response to the increasing pressure on academic researchers to pursue commercial applications of their research in the lab and clinical practice. *Id.*



when they pursue patents on research tools, and therefore state universities should receive no beneficial treatment for licensing their technologies.<sup>144</sup>

Alternatively, a two-tier licensing program could be implemented. In a two-tier program, the first tier is the reasonable royalty calculated as described, while the second tier is a reduced royalty option available to those who would similarly qualify for Small Entity Status under the United States Patent and Trademark Office guidelines.<sup>145</sup> Under these guidelines, individual inventors, small businesses or non-profit institutions (including universities) qualifying for Small Entity Status pay reduced fees for procuring a patent.<sup>146</sup> This assures the costs of patenting an invention do not prohibit small entities from attaining patent protection. Extending this assurance to the proposed compulsory licensing scheme would further protect the interests of academic and other non-profit inventors, whose primary source of income is the federal government.

Under the proposed compulsory licensing scheme, the overall result in *Madey* may or may not be similar to the Federal Circuit's decision. If the court found *Madey's* laser to be a research tool (arguably "equipment" in the NIH list), then Duke University would be forced to license the laser from *Madey*, and *Madey* could not refuse to grant a license. However, if the court found the laser was not included in the list of research tools, *Madey* could deny Duke University access to the laser altogether.

The Federal Circuit remanded the *Madey* case to the district court on several grounds and the Supreme Court recently denied certiorari.<sup>147</sup> One of the remedies presently available to the court is compulsory licensing to compensate *Madey* for the infringing activities of Duke University. Regardless of the outcome in the district court, it is clear the Federal Circuit indicated academic institutions receive no particular protection from patent infringement liability under the experimental use exemption.

#### IV. CONCLUSION

While the Federal Circuit has maintained a "truly narrow" experimental use exemption, this narrow exemption is no longer practical. Both academic and industrial scientists admit access to patented inventions does not usually come easy.<sup>148</sup> Furthermore, the Bayh-Dole Act allowed academic institutions to pursue patent protection for federally funded research.<sup>149</sup> This has dramatically increased the overall number of patents pursued, as well as complicated the academic claim to an experimental use exemption.<sup>150</sup>

The compulsory licensing scheme proposed in this article allows Congress to ensure patent holders receive compensation for the use of their property rights, while

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<sup>144</sup> *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002), *cert. denied*, 123 S.Ct. 2639 (2003).

<sup>145</sup> 37 C.F.R. § 1.27 (2000).

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

<sup>147</sup> *Madey*, 307 F.3d at 1364, *cert. denied*, 123 S. Ct. 2639 (2003).

<sup>148</sup> NAT'L. ACAD. SCI., *supra* note 86.

<sup>149</sup> Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (codified at 35 U.S.C. §§ 200-11 (2000)).

<sup>150</sup> Valoir, *supra* note 40, at 234.

fellow scientists are provided access to research tools needed to further develop science and technology.