

## MADEY V. DUKE UNIVERSITY: SHATTERING THE MYTH OF UNIVERSITIES' EXPERIMENTAL USE DEFENSE

By Michelle Cai

In *Madey v. Duke University*,<sup>1</sup> the Federal Circuit rejected an experimental use defense to a patent infringement lawsuit against a university.<sup>2</sup> The Federal Circuit considered for the first time the issue of whether a nonprofit research institution accused of patent infringement should be treated any differently from a commercial company. The court held that the experimental use defense does not apply to infringing activities that are “in keeping with the alleged infringer’s legitimate business, regardless of commercial implications.”<sup>3</sup> By defining “legitimate business” broadly, the court practically eliminated the experimental use defense in academic research, causing outcries among universities and nonprofit research institutes who fear that the decision will significantly impede the nation’s scientific progress, especially in the biomedical area.<sup>4</sup>

In reality, *Madey* has merely shattered a long-held myth that universities are immune to patent infringement liability under the experimental use defense. Given the Federal Circuit’s hostility towards the experimental use defense in commercial settings, the *Madey* ruling is hardly a surprise.<sup>5</sup> Pure academic research devoid of commercial implications is becoming a rarity in an era of federal incentives to turn the fruits of government-funded basic research into commercial applications.<sup>6</sup> Moreover, despite their patent infringement activities, universities have not faced infringement liability.<sup>7</sup> Patent holders have traditionally tolerated such infringement because the harm of a lawsuit against a university outweighs its

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1. 307 F.3d 1351 (Fed. Cir. 2002) [hereinafter *Madey II*].

2. *Id.* at 1362.

3. *Id.*

4. Brief of Amici Curiae Association of American Medical Colleges, et al. at 4-5, *Madey v. Duke Univ.*, 207 F.3d 1351 (Fed. Cir. 2002) (No. 02-1007).

5. Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCI. 1018, 1018-19 (2003).

6. *Id.*

7. *Id.* at 1019 (“[Research universities] have largely ignored the growing number of patents covering technology that their scientists use without license and without apology.”); John P. Walsh et al., *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (2003).

benefit.<sup>8</sup> In other words, patent holders have exercised a rational forbearance.

This Note examines the impact of the *Madey* decision on academic research. Part I provides a background of the doctrine of the experimental use defense as well as the commercialization phenomenon in academic research environment. Part II describes the *Madey* case, focusing on the issue of the experimental use defense. Part III assesses the *Madey* decision in the context of academic research. Part III.A analyzes the Federal Circuit's interpretation of the experimental use defense to understand whether the defense still has any practical meaning in academic settings. Part III.B discusses the decision's implications on academic research. Part III.B also argues that although *Madey* may send a chilling message to universities that academic research is not shielded from patent infringement lawsuits, the risk of lawsuits remains small because patent holders will likely continue to exercise rational forbearance. Part III.C addresses the problem of broad patents on upstream research tools and argues against expanding the experimental use defense in this area. The Note concludes that, despite its potentially chilling effect, *Madey* is not likely to adversely affect the way research is conducted in universities today.

## I. BACKGROUND

### A. The Experimental Use Defense

The experimental use defense is a common law doctrine that exempts certain acts from patent infringement liability if they are conducted solely for the purpose of scientific inquiry.<sup>9</sup> The doctrine originated in Justice Story's 1813 opinion in *Whittemore v. Cutter*,<sup>10</sup> following the rationale that "it could never have been the intention of the legislature to punish a man, who constructed [an infringing device] merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."<sup>11</sup>

Subsequent cases have limited the doctrine to very narrow grounds.<sup>12</sup> In *Pitcairn v. United States*,<sup>13</sup> the Court of Claims held that the United

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8. See Walsh et al., *supra* note 7, at 1021.

9. It is also referred to as the research exemption or the experimental use exception. These terms will be used interchangeably in this Note.

10. 29 F. Cas. 1120 (C.C.D. Mass. 1813).

11. *Id.* at 1121.

12. See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17-18 (2001).

States government was not entitled to the experimental use defense where a federal agency's use of plaintiff's patented helicopters for testing purposes was in keeping with the agency's legitimate business.<sup>14</sup> The court found that the government was not immune from patent infringement liability, notwithstanding the lack of commercial implications of its use.<sup>15</sup>

The Federal Circuit considered for the first time the experimental use defense in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*<sup>16</sup> Bound by *Pitcairn*, the Federal Circuit held that the experimental use defense is "truly narrow" and only applies to activities "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>17</sup> The court reasoned that Bolar's experimentation on Roche's patented pharmaceutical product was not the kind of "dilettante affair" envisioned by Justice Story, but was solely for commercial purposes.<sup>18</sup> Thus, the court stated that the experimental use defense does not apply to a scientific inquiry which has "definite, cognizable, and not insubstantial commercial purposes."<sup>19</sup>

Congress partially overruled the holding of *Roche* by enacting the Hatch-Waxman Act, which in part provides a safe harbor for experimentation solely for the purpose of generating FDA-required test data.<sup>20</sup> Even so, the experimental use defense remains narrow outside the safe harbor. In *Embrex, Inc. v. Service Engineering Corp.*,<sup>21</sup> for example, the Federal Circuit reaffirmed its narrow interpretation of the experimental use exception by rejecting the defense because the defendant's tests were "expressly for commercial purposes."<sup>22</sup>

Neither the Federal Circuit nor any of its predecessors, however, addressed the issue of a nonprofit research institution's exemption under the experimental use defense until very recently. In fact, throughout the doctrine's nearly two hundred years of existence before *Madey*, only one reported opinion, *Ruth v. Stearns-Roger Manufacturing Co.*,<sup>23</sup> ever dealt with this issue. There, the court held that the experimental use of patented

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13. 547 F.2d 1106 (Ct. Cl. 1976).

14. *Id.* at 1125-26.

15. *See id.*

16. 733 F.2d 858, 863 (Fed. Cir. 1984) (rejecting the experimental use defense where Bolar had experimented on one of Roche's patented drugs in order to generate test data for filing a generic drug application at the FDA).

17. *Id.* at 863.

18. *Id.*

19. *Id.*

20. *See* 35 U.S.C. § 271(e) (2000).

21. 216 F.3d 1343 (Fed. Cir. 2000).

22. *Id.* at 1349.

23. 13 F. Supp. 697 (D. Colo. 1935).

machines in the laboratory of a university, Colorado School of Mines, did not constitute infringement.<sup>24</sup> The defendant in that case was not the university directly, but a commercial company accused of contributory infringement for selling replacement parts for the patented machines to the university.<sup>25</sup>

Despite the lack of case law to define the boundaries of the experimental use defense, academic researchers have by and large ignored patent rights in carrying out their research.<sup>26</sup> Universities and university researchers assume that research activities for noncommercial purposes are exempt.<sup>27</sup> The assumption is arguably implied by language in the Federal Circuit's *Roche*<sup>28</sup> and *Embrex*<sup>29</sup> opinions, which focuses on the commercial purposes of the infringing uses. The absence of patent infringement lawsuits against universities also reinforces such an assumption.<sup>30</sup>

## **B. The Growing Role of Universities in Commercializing Scientific Discoveries**

Since the passage of the Bayh-Dole Act in 1980,<sup>31</sup> universities have increasingly participated in commercializing their research discoveries, blurring the distinction between pure scientific research and commercial research.<sup>32</sup> The Bayh-Dole Act allows universities to patent federally funded inventions and thereby encourages universities to commercialize

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24. *Id.* at 703.

25. *Id.*

26. See Eyal H. Barash, *Experimental Use, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667, 698 (1997) ("University researchers rarely check the patent literature to determine whether their proposed research will infringe on any patents."); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 324 (Wesley M. Cohen & Stephen Merrill eds., 2003).

27. Brief of Amici Curiae Association of American Medical Colleges, et al. at 11, *Madey v. Duke Univ.*, 207 F.3d 1351 (Fed. Cir. 2002) (No. 02-1007).

28. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (denying experimental use defense where the court found that Bolar's experimentation had "definite, cognizable, and not insubstantial commercial purposes").

29. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (denying defendant SEC's experimental use defense on the basis of district court's finding that the experimental tests performed by SEC were "expressly for commercial purposes")

30. See Walsh et al., *supra* note 26, at 325.

31. Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212.

32. See, e.g., Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Sciences in Biotechnology Research*, 97 YALE L.J. 177, 195-97 (1987); Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291-95 (2003).

the results of their basic research.<sup>33</sup> Universities are now active players in the patent arena. Prior to 1981, fewer than 250 patents were issued to universities per year;<sup>34</sup> in less than twenty years, that number increased to over 3000.<sup>35</sup> Universities' share of United States corporate-owned patents has also steadily increased.<sup>36</sup> To generate revenue out of their patented technologies, universities not only actively seek prospective licensees in the industry, but aggressively sue commercial companies for patent infringement.<sup>37</sup> Two large settlements in 1999, Genentech's \$200 million to the University of California and Glaxo-Wellcome's \$300 million to the University of Minnesota, have spurred a wave of patent infringement lawsuits by universities.<sup>38</sup> Universities' commercial interests also go beyond patented technologies. Encouraged by the federal government, universities receive funding from industry and form collaborative relationships with for-profit companies.<sup>39</sup>

While some hail the Bayh-Dole Act as a success in promoting technology transfer from universities to companies for commercial development, both patent law scholars and research scientists have raised serious questions about the long-term impact of universities' patenting practice.<sup>40</sup> Universities' patents are mostly derived from basic research and tend to be upstream of product development.<sup>41</sup> Such patents, if enforceable, are po-

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33. The stated policy objective of the Bayh-Dole Act is "to use the patent system to promote the utilization of inventions arising from federally supported research or development . . ." 35 U.S.C. § 200.

34. The Council on Governmental Relations, University Technology Transfer, Questions and Answers, No. 1, at <http://206.151.87.59/docs/BayhDoleQA.htm> (Nov. 30, 1993) [hereinafter Questions & Answers].

35. Technology Assessment and Forecast (TAF) Branch, U.S. Patent and Trademark Office, U.S. Colleges and Universities—Utility Patent Grants, Calendar Years 1969-2000, at [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table\\_1.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/univ/asgn/table_1.htm) (last modified May 14, 2002).

36. See *id.* For statistical purposes, U.S. corporations include both universities and nonuniversities.

37. Eisenberg, *supra* note 5, at 1018.

38. *Id.* Academic institutions that have filed patent infringement lawsuits against large corporations include Baylor College of Medicine, Cornell University, Columbia University, University of Rochester, University of California and the Massachusetts Institute of Technology. *Id.*

39. Questions & Answers, *supra* note 34, No. 13.

40. See, e.g., Rai & Eisenberg, *supra* note 32, at 290-91 (criticizing the Bayh-Dole Act for drawing no distinction between upstream basic research and downstream commercial development and arguing that patenting upstream fundamental technologies will restrict rather than promote utilization of the technologies).

41. See Ted Agres, *The Costs of Commercializing Research*, 17 SCIENTIST 58 (2003) (quoting Nobel Laureate Paul Berg's comment: Bayh-Dole "is likely to damage

tentially of a very broad scope because they also claim downstream future discoveries and seek reach-through royalties based on sales of products ultimately developed using the patented technologies.<sup>42</sup> Another issue is that universities often grant exclusive rather than nonexclusive licenses to companies and investors because of the risk associated with investing in upstream technology.<sup>43</sup> In genetic research, for example, 68% of licenses granted by universities are exclusive, as compared with only 27% by private companies.<sup>44</sup> Thus, because of their broad scope and exclusive licensing, university patents may not only have huge commercial value but also prevent others from developing downstream technologies.<sup>45</sup>

## II. CASE SUMMARY

Dr. John M.J. Madey (“Madey”) sued his former employer, Duke University (“Duke”), in the United States District Court for the Middle District of North Carolina for infringing his patents on research equipment.<sup>46</sup> Duke moved for partial summary judgment, asserting among other defenses the experimental use defense.<sup>47</sup> The district court granted summary judgment in favor of Duke, holding that the experimental use defense applied to the university’s use because Madey had failed to establish that the use had any commercial purpose.<sup>48</sup> On appeal, the Federal Circuit reversed and remanded for further proceedings.<sup>49</sup>

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the health of the scientific enterprise in the long term, notwithstanding the financial benefits in the short term”), available at [http://www.the-scientist.com/yr2003/avg/profl\\_030825.html](http://www.the-scientist.com/yr2003/avg/profl_030825.html) (Aug. 25, 2003); Rai & Eisenberg, *supra* note 32, at 292 (observing that university-owned patents tend to cover fundamental research discoveries and research tools rather than commercial end products).

42. Rai & Eisenberg, *supra* note 32, at 296-97.

43. Walsh et al., *supra* note 26, 309.

44. *Id.* However, only about 15% of university-based inventions are patented. *Id.*

45. In limited circumstances, the Bayh-Dole Act does authorize government funding agencies to withhold title to government-funded inventions or to exercise “march-in rights” to compel licensing of such inventions. 35 U.S.C. §§ 202(a)-(b), 203. However, the administrative procedure is sufficiently cumbersome that agencies such as the National Institute of Health have rarely exercised these oversight rights. See Rai & Eisenberg, *supra* note 32, at 293-94.

46. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420, 424 (M.D.N.C. 2001) [hereinafter *Madey I*].

47. *Id.*

48. *Id.* at 428.

49. *Madey II*, 307 F.3d 1351, 1364 (Fed. Cir. 2002).

## A. Facts

Madey is a renowned scientist and scholar in the field of electromagnetic radiation research.<sup>50</sup> In 1989, while a tenured professor at Stanford University, Duke University recruited Madey to establish a free electron laser laboratory (“FEL lab”) and research program at Duke.<sup>51</sup> At Stanford, Madey had obtained sole ownership of two patents, U.S. Patent No. 4,641,103 (“the ’103 patent”) and U.S. Patent No. 5,130,994 (“the ’994 patent”), covering some of the equipment in his FEL lab, which he moved from Stanford to Duke.<sup>52</sup>

Madey served as the director of the FEL lab at Duke for almost a decade.<sup>53</sup> During that time, Madey’s lab made scientific breakthroughs and Madey helped Duke obtain research funding.<sup>54</sup> In 1997, however, Madey was removed from the director position following a dispute with the university.<sup>55</sup> Subsequently, Madey resigned from Duke, but the university continued to operate some of the patented equipment in the lab.<sup>56</sup> Madey brought suit against Duke alleging, among other things, that Duke had infringed the ’103 and ’994 patents by using three devices at the FEL lab, two of which belonged to Duke.<sup>57</sup>

## B. The District Court’s Ruling

On the basis of the experimental use defense, the district court granted Duke’s motions for partial summary judgment on the patent infringement claims concerning the devices belonging to Duke.<sup>58</sup> The court reasoned that the experimental use defense may be asserted in cases where the allegedly infringing use is “for experimental, nonprofit purposes only.”<sup>59</sup> The court found that Madey had failed to establish by a preponderance of the evidence that Duke’s infringing use was not solely for experimental or other nonprofit purposes.<sup>60</sup> Focusing its analysis on Duke’s nonprofit

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50. *Madey I*, 266 F. Supp. 2d at 421.

51. *Madey II*, 307 F.3d at 1352.

52. *Id.* at 1352-53.

53. *Id.* at 1352.

54. *Id.*

55. *Id.* at 1352-53.

56. *Id.* at 1353.

57. *Id.* The third device belonged to a third party, North Carolina Central University. *Id.* At trial, the district court did not find infringement on the third party’s device because Madey had consented to its manufacture and use, and Madey did not appeal this issue. *Id.* at 1357.

58. *Madey I*, 266 F. Supp. 2d 420, 424-28 (M.D.N.C. 2001).

59. *Id.* at 425.

60. *Id.* at 426.

status, the court concluded that Madey was merely speculating that Duke intended to use the devices covered by his patents for commercial benefit and thus failed to create a genuine issue of material fact.<sup>61</sup>

### C. The Federal Circuit's Ruling

The Federal Circuit reversed the district court's decision on the experimental use defense on three grounds. First, the Federal Circuit found that the lower court had improperly shifted the burden onto Madey to prove that Duke's use of his patented equipment was not experimental.<sup>62</sup> Agreeing with Madey, the Federal Circuit held that the experimental use defense must be established by the defendant.<sup>63</sup>

Second, the Federal Circuit held that the district court's conception of the experimental use defense was "overly broad" and inconsistent with the Federal Circuit's binding precedent.<sup>64</sup> According to the Federal Circuit, the experimental use defense is "very narrow and strictly limited."<sup>65</sup> Reiterating its holdings in *Roche* and *Embrex*, the Federal Circuit stated that the experimental use defense is limited to uses "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," and that the defense is disqualified as long as a use has any "definite, cognizable, and not insubstantial commercial purposes."<sup>66</sup> Relying on *Pitcairn*, the Federal Circuit also disqualified any conduct from the experimental use defense if the conduct was in keeping with an infringer's legitimate business, "regardless of commercial implications."<sup>67</sup> The court stated that the legitimate business of a research university includes any project designed to "educat[e] and enlighten[] students and faculty," to "increase the status of the institution," or to "lure lucrative research grants, students and faculty."<sup>68</sup>

Third, the Federal Circuit found that the district court had placed too much emphasis on Duke's nonprofit status, and thus failed to consider specific facts that tended to indicate the university's use was in keeping

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61. *Id.* at 426-28. Given the court's ruling on the experimental use issue, Duke's alternative argument that its uses of the Madey patents were covered by a government license was rendered moot. *Id.* at 429.

62. *Madey II*, 307 F.3d at 1361.

63. *Id.* However, the Federal Circuit refused to label the experimental use defense as an affirmative defense which a defendant must either plead or lose. *Id.*

64. *Id.* at 1361-62.

65. *Id.* at 1361.

66. *Id.* at 1362 (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

67. *Id.*

68. *Id.*

with its legitimate business.<sup>69</sup> On remand, the Federal Circuit required the district court to focus instead on Duke's legitimate business and whether or not Duke's experimental use was "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>70</sup>

### III. DISCUSSION

#### A. *Madey* Effectively Disqualifies All Research Universities and Nonprofit Research Institutes from the Experimental Use Defense

In *Madey*, the Federal Circuit attempted to clarify the murky boundary of the experimental use defense in the context of academic research. Combining its holdings in *Embrex*,<sup>71</sup> *Roche*,<sup>72</sup> and *Pitcairn*,<sup>73</sup> the court took one step further toward narrowing the already "very narrow" and "strictly limited" experimental use defense.<sup>74</sup> The Federal Circuit stated that, regardless of commercial implications, an allegedly infringing act does not qualify for the experimental use defense so long as the act is: (1) "in furtherance of the alleged infringer's legitimate business;" and (2) "not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>75</sup>

These two conditions are both very broad and overlap substantially. Under the Federal Circuit's broad definition of "legitimate business," practically any project conducted by a research university, even one without any commercial implications, would be in keeping with the university's legitimate business interests and hence would not qualify for the ex-

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69. *Id.* The court took notice that Duke, like other research universities, was aggressively pursuing a patent licensing program and deriving a "not insubstantial" revenue stream from the program. *Id.* at 1362 n.7.

70. *Id.* at 1362-63. On remand, the Federal Circuit also allowed the district court to reexamine Duke's alternative defense on government license, which became moot after the district court's ruling on the experimental use defense. *Id.* at 1363-64.

71. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (holding that the experimental use defense is limited to use "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry").

72. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that the experimental use defense does not apply to use that has "definite, cognizable, and not insubstantial commercial purposes," but in the "guise of scientific inquiry").

73. *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Fed. Cir. 1976) (holding that the experimental use defense is not available for use in keeping with an alleged infringer's legitimate business).

74. *See Madey II*, 307 F.3d at 1362.

75. *Id.*

perimental use defense.<sup>76</sup> Furthermore, projects in universities, especially in areas where patent infringement issues arise, are rarely carried out “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” Moreover, those “solely for amusement” or “solely . . . to satisfy idle curiosity” generally do not fit into the legitimate business of research universities. A university typically does not design projects *solely* for “amusement” or “curiosity” purposes.

The remaining question then is what constitutes conduct “solely . . . for strictly philosophical inquiry.”<sup>77</sup> The term “philosophical” originated in Justice Story’s opinion in *Whitmore v. Cutler*,<sup>78</sup> and “philosophical inquiry” likely means what we call “scientific inquiry” today.<sup>79</sup> While scientific inquiry encompasses a wide variety of research, only research at the most theoretical end of the spectrum is likely carried out for nothing but pure scientific inquiry and be exempt from patent infringement liability. But such research is unlikely to lead to patent disputes. Thus, in *Madey*, the Federal Circuit has in effect put forth a bright-line rule, practically stripping the experimental use defense from all research universities and nonprofit research institutes.

Nonetheless, some have read *Madey* as a call for a case-by-case “detailed analysis” of each infringing experimental use.<sup>80</sup> The confusion mainly stems from the court’s inconsistent statements regarding the two conditions noted above. The experimental use defense appears to be still available so long as one of the two conditions is not satisfied. Thus, for example, if a university’s infringing conduct is deemed “solely for . . . strictly philosophical inquiry,” then it will be exempted even though such conduct furthers the university’s legitimate business. But such a reading of *Madey* would be inconsistent with the Federal Circuit’s language in the same opinion that “[the court’s] precedent does not immunize *any* conduct that is in keeping with the alleged infringer’s legitimate business.”<sup>81</sup> Per-

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76. *See id.* (providing examples of a university’s legitimate business which include educating and enlightening students and faculty, elevating the university’s status, and attracting research grants, students and faculty).

77. Curiously, while providing a detailed explanation for the meaning of “legitimate business,” the Federal Circuit did not elaborate on the definition of “strictly philosophical inquiry.” *See id.*

78. 29 F. Cas. 1120 (C.C.D. Mass. 1813).

79. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 n.8 (Fed. Cir. 2003) (Newman, J., dissenting).

80. *See* Brief of Amicus Curiae the United States at 13, *Madey II*, 207 F.3d 1351 (Fed. Cir. 2002) (No. 02-1007) (submitted by the Solicitor General at the invitation of the Supreme Court) (quoting Pet. App. 25a).

81. *Madey II*, 307 F.3d at 1362 (emphasis added).

haps the Federal Circuit could have been clearer if it had used the connector “or” between the two conditions rather than “and.” Then, since all research projects of an academic institution are in keeping with the institution’s legitimate business, none will be exempt under the experimental use defense.

### **B. *Madey’s Implications for Academic Research in Universities and Nonprofit Institutes***

Denying the experimental use defense to universities and nonprofit institutes could have a chilling effect on academic research. A significant portion of university research is basic research that contributes to the general understanding of science but has no direct commercial applications. Under *Madey*, most basic research will not be exempt because it is not pure scientific inquiry; yet it is remote from commercial applications. In order to avoid patent infringement, universities may have to devote resources to perform costly patent searches and engage in licensing negotiations with patent holders. Concurrent fragments of Intellectual Property (IP) rights may lead to bargaining breakdowns.<sup>82</sup> Even without breakdowns, royalty stacking of downstream discoveries through reach-through licenses could significantly increase costs of doing research.<sup>83</sup> Also, patent transactions can slow down research and impede free flow of scientific information.<sup>84</sup>

Despite its potential chilling effect, *Madey* is unlikely to change the way research is carried out in universities today. Even before *Madey* rational forbearance was the norm, and is likely to remain so. Patent infringement is prevalent in universities.<sup>85</sup> Many of universities’ infringing activities could be interpreted to have “definite, cognizable, and not insubstantial commercial purposes” under *Roche*,<sup>86</sup> and yet patent holders have generally tolerated such conduct.<sup>87</sup> A recent survey of biopharmaceutical companies and universities on how research tool patents affect biomedical research reveals that commercial companies are unlikely to sue universities for patent infringement for several reasons.<sup>88</sup> First, experimental use conducted in research universities can benefit the patent holders by in-

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82. Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998).

83. *Id.*

84. *Id.*

85. Walsh et al., *supra* note 7, at 1021.

86. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

87. Walsh et al., *supra* note 7, at 1021.

88. *Id.*

creasing the value of the patented technologies.<sup>89</sup> Second, commercial companies hoping to gain access to materials and information from university researchers do not want to lose the goodwill of the research community by upsetting its norms of open access.<sup>90</sup> Third, and more importantly, the small gains from a lawsuit do not justify the high legal costs, the risk of patent invalidation, and the bad publicity from suing a university.<sup>91</sup> Universities are even less likely to sue other universities.<sup>92</sup>

Such "rational forbearance" has been the norm governing the relationship between patent holders and universities. Because the reasons for doing so in the past still exist after *Madey*, patent holders will likely continue to exercise rational forbearance and refrain from suing universities, even for projects with arguably commercial implications. For research projects without commercial implications, the chances of a university being sued are even slimmer, even if the experimental use defense is unavailable.

Some might argue that just as universities' attitude toward licensing copyrighted materials for classroom use has significantly changed since a 1991 decision, *Basic Books, Inc. v. Kinko's Graphics, Corp.*,<sup>93</sup> so will universities' policy regarding in-bound patent licensing for research purposes change after *Madey*. In *Kinko's*, eight publishers sued a commercial photocopy center for copyright infringement because it copied excerpts from books without permission, combined them into course packets, and sold them to college students.<sup>94</sup> In ruling against *Kinko's*, the court reasoned that although the course packets were used for educational purposes, the copy center made the copies for profit and the making of course packets therefore did not constitute fair use.<sup>95</sup> While both *Madey* and *Kinko's* involved IP infringement in academic settings and in both cases the IP rights were enforced, the plaintiffs and defendants in these cases were very different. *Kinko's* involved two commercial entities, namely publishers and a photocopy center, whereas the dispute in *Madey* is between a disgruntled former employee and a university.

The lesson from *Kinko's* was that publishers can better enforce their IP rights indirectly through pursuing commercial photocopy centers rather than suing the direct infringers, namely universities and their faculty and students. Eight years before *Kinko's*, New York University (NYU) was

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89. *Id.*

90. *Id.*

91. *Id.*

92. Walsh et al., *supra* note 26, at 327.

93. 758 F. Supp. 1522 (S.D.N.Y. 1991).

94. *Id.* at 1526.

95. *Id.* at 1530-35.

sued by publishers for copyright infringement when the university engaged in widespread photocopying of copyrighted materials for classroom use without permission.<sup>96</sup> As a condition for settling the suit, NYU pledged to step up its efforts in enforcing a pre-existing classroom photocopying guideline.<sup>97</sup> However, the university's pledge had little effect on its faculty and students; rampant classroom copyright violations continued.<sup>98</sup> It was not until after *Kinko's*, where a commercial copy center was found liable for copyright infringement, that universities started to acquire licenses for classroom photocopying through copy centers.<sup>99</sup> *Kinko's* infringing copying was done for university students, including those of NYU.<sup>100</sup> This time, rather than dragging in the universities as co-defendants, the publishers only sued the copy center. For settlement, *Kinko's* paid the publishers \$1,875,000 and was barred from supplying course packets for 10 years.<sup>101</sup> The settlement appears to have created enough deterrence since commercial copy centers are no longer willing to photocopy for universities without permission from the publishers.<sup>102</sup>

Like the publishers in *Kinko's*, commercial patent holders are likely to avoid suing universities if they can find commercial targets. If a patented research tool is commercialized, the patent holder may indirectly enforce the IP rights by suing the unlicensed commercial suppliers of the tool. For example, Hoffman-La Roche ("Roche") aggressively pursued a commercial reagent supplier, Promega, for infringing Roche's patents on *Taq* polymerase used in polymerase chain reaction ("PCR"), a basic research tool widely used in life science research.<sup>103</sup> Although Roche accused over forty universities and research institutes and over 200 academic researchers of infringing their patents, it did not bring suits against any of these end-users.<sup>104</sup> By suing the reagent supplier, Roche achieved the same result of

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96. ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES 259-60 (1991) (citing Addison-Wesley Publ'g v. N.Y. Univ., No. 82 Civ. 8333, 1983 WL 1134 (S.D.N.Y. May 31, 1983)).

97. *Id.* at 260.

98. *Id.*

99. *See* Princeton Univ. Press v. Mich. Document Servs., Inc., 99 F.3d 1381, 1384 (6th Cir. 1996).

100. *Kinko's*, 758 F. Supp. at 1526.

101. Basic Books, Inc. v. Kinko's Graphics Corp., No. 89 Civ. 2807 (CBM), 1991 WL 311892, at \*1-2 (S.D.N.Y. Oct. 16, 1991) (awarding the publishers \$510,000 in statutory damages and \$1,365,000 in attorneys' fees and costs); Publishers Weekly, *Kinko's Re-enters Coursepack Market*, Sept. 22, 2003, available at [http://www.publisher-weekly.reviewsnews.com/esecc/Article\\_324109.htm](http://www.publisher-weekly.reviewsnews.com/esecc/Article_324109.htm).

102. *See* Princeton Univ. Press, 99 F.3d at 1384.

103. Mueller, *supra* note 12, at 3.

104. *Id.*

collecting royalties from academic end-users, but without breaking the norms of the research community. For do-it-yourself type of patented inventions, enforcement will be harder because no commercial entities are between patent holders and universities. Nonetheless, except for clinical research using patented diagnostic tests, patent holders have generally left university researchers alone.<sup>105</sup>

*Madey* is the first case where a university was sued for patent infringement, but its fact pattern is highly unusual. *Madey* owned the patent while the vast majority of patents derived from university research are contractually assigned to universities rather than to individual inventors.<sup>106</sup> In the wake of *Madey*, universities may become more wary about relinquishing their IP rights to their employee inventors.

The more typical patent infringement suits from commercial companies have yet to be brought against universities. While some universities and university researchers have received letters of notification of infringement from patent holders, such letters are very rare and the majority of them do not present a real threat.<sup>107</sup> Occasionally, universities have entered patent licenses at the request of patent holders.<sup>108</sup> While some research universities may have taken steps in educating their researchers about respecting other people's IP rights, universities are not likely to go out of their way to search for patents in order to avoid infringement. Until they are seriously threatened by lawsuits, universities have no incentive to police their own researchers.

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105. Walsh et al., *supra* note 26, at 317.

106. However, inventors are entitled to share a part of the patents' licensing profits. For example, the University of California allows 35% of net royalty income to be allocated to inventors for personal use, 15% for inventor's research and 50% to the university for general campus use. Other major research universities use other formulae to distribute royalty income between inventors and the universities. See Office of Technology Transfer, Univ. of Cal., Patent Policy, at <http://www.ucop.edu/ott/patentpolicy/pat-pol.html> (last visited Mar. 16, 2004) (including royalty distribution formula of the University of California and eleven other major research universities).

107. Walsh et al., *supra* note 26, at 317.

108. For example, many universities have taken out a license from DuPont for the cre-lox patent. The license does not require the universities to pay a fee to use the technology, although it does contain reach-through provisions on income generated by the universities through the use of the technology. See Office of Technology Transfer, Univ. of Cal., Memo: Operating Guidance, No. 98-01 (June 30, 1998) (summary of problems with the DuPont Cre-Lox License), at <http://patron.ucop.edu/ottmemos/docs/ott98-01.html>.

### C. A Critique of Arguments for Expanding the Experimental Use Defense

Scholars and judges have advocated a broader experimental use exception to exempt certain socially beneficial infringing activities. For example, Rebecca Eisenberg proposes an exemption for research that could potentially lead to an improvement or a design-around of a patented invention.<sup>109</sup> She recommends a royalty after the fact under certain circumstances to allow the patent holders to receive adequate return on their initial investments.<sup>110</sup> The rationale is that if a competitor is required to pay royalties before the fact, a patent holder may be reluctant to license the rights to a competitor.<sup>111</sup> Under this proposal, most infringing uses in research will be exempt, including many with commercial purposes. Such an outcome, however, cannot be squared with the Federal Circuit's precedent as postulated in *Roche*<sup>112</sup> and *Embrex*.<sup>113</sup>

Allowing the experimental use exception may be justifiable in areas where patent exclusion produces socially harmful results. For example, Heller and Eisenberg argue that an anticommons tragedy could occur either when too many patent holders concurrently own fragments of patent rights in a future product or when too many upstream patent holders stack licenses on top of downstream discoveries.<sup>114</sup> However, there is little empirical evidence to support the anticommons theory.<sup>115</sup> Patent rights of upstream research discoveries rarely stifle downstream research activities. Although marginal projects are sometimes impeded, worthwhile projects are almost never stopped for lack of IP access.<sup>116</sup> University and industry researchers use creative "working solutions" to get around IP barriers.<sup>117</sup> Such solutions include licensing, designing around, going offshore, developing public databases and research tools, challenging in courts, or simply using a patented invention without permission and hoping the patent holders will not notice or bother to sue.<sup>118</sup>

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109. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989).

110. *Id.*

111. *See id.* at 1082.

112. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

113. *See Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

114. Eisenberg, *supra* note 82, at 698.

115. *See Walsh et al.*, *supra* note 26, at 297-305.

116. *Id.* at 303-05.

117. *Id.* at 322-36.

118. *Id.*

A problem with expanding the experimental use exemption is determining where to draw a line between exempted and nonexempted research categories. In her dissenting opinion in *Integra*, Judge Newman voiced her discontent with the *Madey* court's sweeping statement on research exemption.<sup>119</sup> Focusing on the so-called "research tools," which can be broadly defined to include any product or method used in the course of research, she made a distinction between "[u]se of an existing tool in one's research" and "study of the tool itself."<sup>120</sup> The former category is intended for studying subject matters outside the technology of the tool, whereas the latter may lead to improvements on that particular technology. She would exempt the latter category but not the former.<sup>121</sup> However, this distinction is not always meaningful in practice, because the use of an existing tool in one's research is often commingled with study of the tool itself; one could be improving the tool while using it to study something else. Moreover, patented inventions involved in both types of research stimulate innovation and thus there is no reason to give protection to one but not the other.<sup>122</sup>

A division of exempted and nonexempted research activities based on commercial implications would not make sense in today's research environment either. With universities' growing role in commercialization, the distinction between pure scientific inquiry and commercially motivated research is smudged. Gone are the days where scientific research was conducted "solely for . . . strictly philosophical inquiry." Without making claims to some practical implications, such as finding a cure for cancer or AIDS, scientists are hard pressed to get funding for their research.<sup>123</sup> Should such claims, however attenuated they are to the ultimate goal disqualify scientists from the experimental use defense?

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119. See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting).

120. *Id.*

121. *Id.*

122. See David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 634-36 (1994).

123. For example, one of the most important federal funding agencies, the National Science Foundation, evaluates research grant proposals based not only on the intellectual merits but also on the broader impacts of the proposed research activities. One of the five broader impacts of a proposed research project is its benefits to society. Examples of activities that benefit society include projects that have "potential application of research and education results" and those that can be integrated into "broader programs and activities of national interest." Nat'l Sci. Found., Merit Review Broader Impacts Criterion: Representative Activities, at <http://www.nsf.gov/pubs/2002/nsf022/bicexamples.pdf> (last visited Nov. 12, 2003).

A solution is to allow government funding agencies such as the National Institute of Health (NIH) to exempt certain research activities from patent infringement liability. Rai and Eisenberg argue that the funding agencies are in a better position to draw the line than the court because they have more expertise in evaluating a technology and its policy implications as well as an effective means to enforce the policy decision through the funding channel.<sup>124</sup> However, it is difficult even for agencies like the NIH to draw the line beyond providing a broad guideline.<sup>125</sup> As acknowledged a few years ago by Harold Varmus, the then NIH director, the NIH does not know how to measure the effect of the agency's decisions in increasing the productivity of the scientific community.<sup>126</sup> As such, the NIH may not be any better than the courts in drawing the appropriate line between exempt and nonexempt research.

Another solution is a bright-line rule eliminating the experimental use defense for universities. This solution is not unfair to the universities. Universities aggressively enforce their patent rights; as such they too should be subject to liability when they infringe others' patents. Although universities may lose some bargaining power in settlement negotiations, they would in most circumstances still be able to get away with infringing uses because of the patentee's rational forbearance.<sup>127</sup> Furthermore, state universities have an additional layer of protection based on the state sovereign immunity doctrine, even though institutional constraints will likely prevent states from adopting policies that violate IP law.<sup>128</sup>

Furthermore, rather than expanding the experimental use defense, the concern about broad upstream patents is better addressed using other aspects of patent law. Overbroad upstream patents may be rejected or invalidated for lack of utility,<sup>129</sup> novelty,<sup>130</sup> enablement or written description.<sup>131</sup>

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124. Rai & Eisenberg, *supra* note 32, at 310-13.

125. See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, National Institute of Health, 64 Fed. Reg. 72,090 (Dec. 23, 1999), available at <http://www.autm.net/policy/agreements/finalnih.doc>.

126. Intellectual Property Rights and Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, Chapter 6: Perspectives from Different Sectors, February 15-16, 1996 (1997), at <http://books.nap.edu/html/property/6.html>.

127. See Walsh et al., *supra* note 7, at 1021.

128. See Peter S. Menell, *Economic Implications of State Sovereign Immunity from Infringement of Federal Intellectual Property Rights*, 33 LOY. L. REV. 1399, 1403 (2000).

129. A more rigorous showing of utility is required to satisfy the prerequisite of patentability under the guidelines recently issued by the U.S. Patent and Trademark Office (USPTO). See Revised Utility Examination Guidelines, 64 Fed. Reg. 71,441 (Pat. & Trademark Off. Dec. 21, 1999).

Reverse doctrine of equivalents could be invoked if a subsequent improvement is truly significant.<sup>132</sup> Reach-through licenses may be limited if they result in patent misuse charges.<sup>133</sup> Licenses may be found unenforceable if a patentee seeks royalties on subject matter not claimed or supported in the patent.<sup>134</sup> As such, broad upstream patents do not justify expanding the experimental use defense.

In addition, expanding the experimental use defense will do more harm than good in promoting innovations. A broad experimental use exception will likely create uncertainty in patent exclusivity which in turn is likely to diminish incentives for investment, especially in the highly risky biopharmaceutical industry. In fact, universities may overall be worse off if the experimental use defense is broadly applied to nonprofit academic research. Many of the universities' own patents could lose exclusivity with respect to other academic researchers and their perceived value in the eyes of investors may therefore be reduced.

#### IV. CONCLUSION

In *Madey*, the Federal Circuit has essentially destroyed any practical meaning to the experimental use defense. The decision has also shattered the long-held myth about research exemption. However, the *Madey* decision is unlikely to have any significant impact on the way universities carry out academic research; nor will it force universities to step up their efforts to avoid patent infringement in the course of their research.

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130. See, e.g., *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367-68, 1372 (Fed. Cir. 2003) (finding inequitable conduct because the inventor misrepresented experimental results to the USPTO in order to overcome novelty rejection in light of prior art). However, the Federal Circuit found that the district court had erred in finding inequitable conduct in other incidents. It also vacated the district court's ruling invalidating the Roche patent and remanded for reconsideration as to whether the incidents of inequitable conduct were sufficient to render the patent unenforceable. *Id.* at 1372.

131. See, e.g., *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-68 (Fed. Cir. 1997) (invalidating claims to human insulin where Lilly's patent specification only disclosed the DNA sequence for rat insulin).

132. See, e.g., *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991) (reversing a summary judgment of infringement because Genentech raised questions of fact material to the infringement issue that Scripps's patent on Factor VIII:C protein, a blood clotting agent, which Scripps obtained through isolating and purifying from the human blood, does not cover Genentech's Factor VIII:C produced by recombinant DNA technology).

133. Gerald J. Flattmann & Jonathan M. Kaplan, *Licensing Research Tool Patents*, 20 NATURE BIOTECHNOLOGY 945, 945-46 (2002).

134. *Id.*