

## NOTE

## THE EXPERIMENTAL PURPOSE DOCTRINE AND BIOMEDICAL RESEARCH

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INTRODUCTION .....	97
I. THE EXPERIMENTAL PURPOSE DOCTRINE .....	99
A. <i>Origin of the Experimental Purpose Doctrine</i> .....	99
B. <i>Roche, Hatch-Waxman, and the         District Courts' Responses</i> .....	100
C. <i>Madey v. Duke University</i> .....	103
D. <i>Integra Lifesciences I, Ltd. v. Merck KGaA</i> .....	105
II. UNIVERSITIES AND THE BIOTECHNOLOGY INDUSTRY—A REALITY CHECK.....	107
A. <i>Entrepreneurial Universities and Professors</i> .....	108
B. <i>Litigious Universities</i> .....	109
C. <i>Universities Are Not Victims—An Empirical Study</i> .....	111
III. AN ECONOMIC ANALYSIS OF THE EXPERIMENTAL PURPOSE DOCTRINE.....	112
CONCLUSION .....	115

### INTRODUCTION

The experimental use doctrine<sup>1</sup> is a common law rule in patent law that until a few years ago excused accused infringers who made and used patented products or processes on the basis of an experimental, educational, or nonprofit purpose when there was *de minimis* economic injury to the patent owner and *de minimis* economic gain to the infringer.<sup>2</sup> While the application of the experimental purpose doctrine was always

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1. This Note uses “experimental purpose doctrine”, as opposed to terms such as “experimental use defense” and “experimental use exception”, to avoid unnecessary confusion with the rule that allows inventors to test their inventions under certain conditions without triggering the “public use bar” or the “on sale bar” under 35 U.S.C. § 102(b) (2000). See 2 Donald S. Chisum, *Chisum on Patents* § 6.02 (2003).

2. See 5 Chisum, *supra* note 1, § 16.03[1] (2004).

narrow, two recent Federal Circuit decisions indicate that there is not much left under its aegis.<sup>3</sup> In *Madey v. Duke University*, the Federal Circuit strictly limited the application of the experimental purpose doctrine to those endeavors which are “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”<sup>4</sup> A year later, in *Integra Lifesciences I, Ltd. v. Merck KGaA* the Federal Circuit held that the safe harbor provision in the Hatch-Waxman Act<sup>5</sup> would not shield defendants who infringe patents while identifying new drug candidates.<sup>6</sup> Although these two decisions strengthened the protection of patents, they also alarmed some commentators because of their potential negative impact on academic research, particularly biomedical research.<sup>7</sup>

This Note presents both empirical data and an economic analysis of the interaction between universities and the biotechnology industry to show that *Madey* and *Integra* were decided correctly, and that the concerns expressed by *Madey* and *Integra*'s critics are unfounded.

In Part I, this Note reviews the historical development and current status of the experimental purpose doctrine.<sup>8</sup> Next, Part II argues that given that the line between academia and the biotechnology industry has

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3. The federal district courts have original jurisdiction of any civil action arising under any Act of Congress relating to patents. 28 U.S.C. 1338(a) (2000). In 1982, Congress created the Court of Appeals for the Federal Circuit to have exclusive appellate jurisdiction over most cases involving patent issues. 28 U.S.C. 1295(a)(1) (2004). A Federal Circuit decision can be further reviewed by the United States Supreme Court. However, the Supreme Court rarely grants certiorari in patent cases, making the Federal Circuit the court of last resort in most instances. Therefore, U.S. patent law is predominantly shaped by the decisions of the Federal Circuit. See generally 4 Chisum, *supra* note 1, § 11.06 (2004).

4. 307 F.3d 1351, 1361-63 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003). In *Madey*, the Federal Circuit refused to characterize experimental use as affirmative defense. It continued to refer it “as both an exception and a defense.” *Id.* at 1361.

5. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2000)).

6. 331 F.3d 860, 867 (Fed. Cir. 2003).

7. See Nicholas Groombridge & Sheryl Calabro, *Integra Lifesciences v. Merck—Good for Research or Just Good for Research Tool Patent Owners?* 22 BIOTECHNOLOGY L. REP. 462, 463 (2003); Tom Saunders, Case Comment, *Renting Space on the Shoulder of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 262 (2003); see also Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018, 1019 (2003); Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347, 389 (2004).

8. The analysis and arguments presented in this Note apply to both public and private universities (and similarly situated public and private non-profit research institutions). Both public and private entities can invoke the experimental purpose doctrine. It is important to note, however, that in patent infringement suits brought against public universities there may be Eleventh Amendment sovereign immunity issues. See Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Savs. Bank, 527 U.S. 627 (1999) (holding that a federal statute that subjected states to patent infringement suits could not be constitutionally supported). For an argument against state immunity in patent infringement, see generally Brandon White, Comment, *Protecting Patent Owners from Infringement by the States: Will the Intellectual Property Rights Restoration Act of 1999 Finally Satisfy the Court?* 35 AKRON L. REV. 531 (2002).

blurred, if not totally disappeared, patent law should not provide universities and non-profit research institutions special protection under the experimental purpose doctrine. To support this argument, Part II surveys the extensive involvement of universities in industry and presents an empirical study of patent infringement suits between universities and industry. Lastly, Part III presents an economic analysis of the experimental purpose doctrine based on the empirical data presented in Part II. Part III argues that the empirical evidence suggests that universities are not in danger of being overwhelmed by the patent litigation mounted by the biotechnology industry.

## I. THE EXPERIMENTAL PURPOSE DOCTRINE

Every patent is “a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention.”<sup>9</sup> Even though patents create a right in the patent owner to exclude others from practicing the patented invention, this right to exclude is not absolute.<sup>10</sup> This Part reviews one of the limitations on the right of exclusion: the experimental purpose doctrine.

### A. Origin of the Experimental Purpose Doctrine

The experimental purpose doctrine is a common law limitation on patent owners’ right of exclusion. Its history can be traced back to an early nineteenth-century opinion written by Justice Story in *Whittemore v. Cutter*.<sup>11</sup> Noting that the defendant was not making the infringing device for profit, Justice Story explained, “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”<sup>12</sup> Later in *Sawin v. Guild*, Justice Story clarified the holding of *Whittemore*: “the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.”<sup>13</sup>

In the 170 years that followed *Whittemore* and *Sawin*, the experimental purpose doctrine was rarely utilized to excuse infringing

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9. 35 U.S.C. § 154 (2000).

10. See 5 Chisum, *supra* note 1, § 16.03 (2004).

11. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

12. *Id.* at 1121.

13. 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

activities.<sup>14</sup> However, in the few instances when it was invoked it was stated in expansive terms, excusing the making and using of patented products or processes for experimental, educational or nonprofit purposes.<sup>15</sup> For example, in *Ruth v. Stearns Roger Manufacturing Co.*, a district court found that the manufacturer of the infringing equipment was not liable for contributory infringement because the purchaser of the infringing equipment was a school that used the equipment in furtherance of its educational purpose.<sup>16</sup>

### B. Roche, Hatch-Waxman, and the District Courts' Responses

In 1984 the Federal Circuit issued an opinion that narrowed the experimental purpose doctrine's guise significantly. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the Federal Circuit held that the experimental purpose doctrine did not immunize the defendant's infringing activities since they were not for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>17</sup>

Roche owned the patent covering the chemical compound flurazepam hydrochloride, the active ingredient in Roche's successful prescription sleeping pill "Dalmane." Bolar wanted to market a generic version of Roche's sleeping pill once Roche's patent expired in 1984. However, before it could market such generic it needed approval from the Food and Drug Administration (FDA) which could take two years to obtain. Not content to wait until the patent expired to obtain the necessary data for FDA approval, Bolar acquired some flurazepam hydrochloride from a foreign manufacturer and started testing it in mid-1983.

Roche consequently sued Bolar for patent infringement. The district court found no infringement.<sup>18</sup> The Federal Circuit disagreed.<sup>19</sup> The Federal Circuit held that the experimental purpose doctrine did not cover "limited use of a patented drug for testing and investigation strictly re-

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14. See 5 Chisum, *supra* note 1, § 16.03 (2004).

15. *Id.*; see Eisenberg, *supra* note 7, at 1018.

16. 13 F. Supp. 697, 713 (D. Colo. 1935); see also *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305 (N.D. W. Va. 1937) (holding that the defendant was not liable for patent infringement when the defendant, in the course of researching and developing a marble-making machine, experimented with a device covered by the plaintiff's patent); *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (holding that there was no infringement because "the evidence shows that a portion of the ... alloy procured by the defendant was used only for testing and for experimental purposes, and there is no evidence that the remainder was used other than experimentally"); see generally 5 Chisum, *supra* note 1, § 16.03 (2004).

17. 733 F.2d 858, 863 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

18. *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 572 F. Supp. 255, 258 (E.D.N.Y. 1983).

19. 733 F.2d at 860.

lated to FDA drug approval requirements during the last 6 months of the term of the patent.”<sup>20</sup> The court reasoned that Bolar may have intended to perform “experiments,” but the unlicensed experiments it conducted with a view to the adaptation of the patented invention to Bolar’s business was a violation of the rights of the patentee to exclude others from using his patented invention. The court stated, “it is a misnomer to call [Bolar’s] intended use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned.”<sup>21</sup> In conclusion, the Federal Circuit refused to construe the experimental purpose doctrine so as to immunize Bolar’s experiments since such construction would “allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”<sup>22</sup>

The generic drug industry actively lobbied Congress to overrule *Roche*.<sup>23</sup> In response Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (more commonly known as the Hatch-Waxman Act).<sup>24</sup> Hatch-Waxman provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>25</sup>

The purpose of the Hatch-Waxman Act was to bring low cost generic drugs to the market quickly by exempting certain research uses from patent infringement liability. *Roche* was overruled by 35 U.S.C. § 271(e)(1) which created a safe harbor for generic drug makers if their infringing activities were intended to prepare information for FDA

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20. *Id.* at 861.

21. *Id.* at 863.

22. *Id.*

23. See generally Janice M. Mueller, “Dilettante Affair”: *Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 25 (2001).

24. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 35 U.S.C. § 271(e)(1) (2000)).

25. 35 U.S.C. § 271(e)(1) (2000).

approval. The language of § 271(e)(1), however, is broadly written and does not unambiguously delineate the statute's scope.

Consequently, in the years following the enactment of Hatch-Waxman, federal district courts were able to get around the Federal Circuit's narrowing of the experimental purpose doctrine in *Roche* by broadly interpreting the safe harbor provisions of § 271(e)(1). For example, in 1998 a district court in Massachusetts ruled that § 271(e)(1) exempted a pharmaceutical company's activities that allegedly infringed Amgen's patents covering genetically engineered erythropoietin, since the activities were aimed at acquiring FDA approval for a competing product.<sup>26</sup> A district court in New York issued a similar ruling in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*<sup>27</sup> Bristol-Myers Squibb used the intermediates patented by Rhône-Poulenc Rorer to synthesize the cancer drug Taxol in order to develop a closely related compound to compete with Taxol. The court held that even though the allegedly infringing activities did not directly generate data for FDA approval, they were exempt under § 271(e)(1).<sup>28</sup> Likewise, in *Nexell Therapeutics, Inc. v. AmCell Corp.*, a district court in Delaware extended the safe harbor to cover defendant AmCell's pre-clinical activities.<sup>29</sup>

While the district courts were utilizing § 271(e)(1) to circumvent *Roche*, the Federal Circuit sat quietly. For fifteen years the court was silent on the experimental purpose doctrine. During this time period *Roche* was highly criticized. Commentators argued that the court's narrow interpretation of the experimental purpose doctrine should be broadened.<sup>30</sup>

Then in 2000, in the case *Embrex, Inc. v. Service Engineering Corp.*, the Federal Circuit reiterated its holding from *Roche*.<sup>31</sup> It stated that the experimental purpose doctrine only covers those experiments that are "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" and it admonished district courts to "not construe the experimental use rule so broadly so as to allow a violation of the patent laws in the guise of scientific inquiry, when that inquiry has definite, cognizable, and not insubstantial commercial purpose."<sup>32</sup>

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26. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998).

27. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 Civ. 8833, 2001 WL 1512597 (S.D.N.Y. Nov. 27, 2001).

28. The Bristol-Myers Squibb case eventually reached the Federal Circuit, but was resolved on a different ground: the patent in suit was not enforceable because of inequitable conduct during prosecution. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003).

29. 199 F. Supp. 2d. 197 (D. Del. 2002).

30. *See e.g.*, Mueller, *supra* note 23.

31. 216 F.3d 1343 (Fed. Cir. 2000).

32. *Id.* at 1349.

Two years later, in *Madey v. Duke University*, the Federal Circuit narrowed the application of the experimental purpose doctrine even further.<sup>33</sup>

### C. *Madey v. Duke University*

In the 1980's, while a tenured research professor at Stanford University, John Madey invented the free electron laser ("FEL"). In 1988, Duke University's physics department recruited him from Stanford. The following year, Madey moved his FEL research lab to Duke. Included in the items moved to Duke was equipment Madey designed. The equipment incorporated two patents he obtained during his tenure at Stanford.<sup>34</sup>

Madey served as director of the FEL lab at Duke for almost a decade. During his tenure as director of the FEL lab, the lab made many scientific breakthroughs and obtained significant research funding. Nevertheless, a dispute arose between Madey and Duke. Duke contended that Madey managed the lab ineffectively in spite of his scientific expertise. Madey maintained that Duke sought to use the lab's equipment for research outside the allocated scope of certain government funding. He alleged that when he objected to such use, Duke tried to remove him as lab director. In 1997, Duke succeeded in removing Madey as director of the lab. Consequently, Madey resigned from Duke.<sup>35</sup>

Duke, however, continued to use some of the equipment in the FEL lab. In response Madey sued Duke for infringing the two patents incorporated in the equipment, in addition to a variety of other claims.<sup>36</sup>

The district court granted Duke summary judgment on the basis of the experimental purpose doctrine.<sup>37</sup> After noting that there was an exception from infringement liability for unauthorized uses of patented inventions where the uses were for research, academic, or experimental purposes, the court ruled in favor of the university because "[Duke's] primary purpose is to teach, research, and expand knowledge, and to not engage in patent development for the purpose of commercial benefit" and because Madey failed to produce sufficient evidence that Duke's infringement had "definite, cognizable, and not insubstantial commercial purposes."<sup>38</sup>

The Federal Circuit reversed.<sup>39</sup> In reversing the district court's decision, the Federal Circuit could have based its ruling on the fact that

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33. 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

34. *Id.* at 1352.

35. *Id.* at 1352-53.

36. *Id.*

37. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420 (M.D. N.C. 2001).

38. *Id.* at 426-27.

39. 307 F.3d at 1352.

Duke's activities did not fall within the narrow boundaries of the experimental purpose doctrine as set forth in *Roche* and *Embrex*. Duke was not tinkering with the equipment to understand Madey's inventions better, therefore its infringing activities were not excused. The court's holding, however, was not based upon past delineations of the doctrine. In issuing its holding in *Madey*, the Federal Circuit further limited the scope of the experimental purpose doctrine.

The Federal Circuit started its opinion in *Madey* by chastising the district court for having an "an overly broad conception of the very narrow and strictly limited experimental use defense", exactly what it instructed district courts not to do in *Embrex*.<sup>40</sup> It then criticized *Ruth v. Stearns Roger Manufacturing Co.*, one of the cases that the district court's decision was based upon.<sup>41</sup> The Federal Circuit criticized *Ruth* as being inconsistent with its holdings in *Embrex* and *Roche*.<sup>42</sup> It supported this criticism by observing the inherently commercial characteristics of research universities:

Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.<sup>43</sup>

The court then restated what activities qualify for the experimental purpose doctrine:

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

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40. *Id.* at 1361.

41. *Id.* at 1362 (citing *Ruth v. Stearns-Roger Manufacturing Company*, 13 F. Supp. 697, 713 (D. Colo. 1935)).

42. *Id.*

43. *Id.* at 1362.



Moreover, the profit or nonprofit status of the user is not determinative.<sup>44</sup>

In remanding the case to the district court, the Federal Circuit left little hope that Duke could use the experimental purpose doctrine as a defense. The Federal Circuit criticized the district court for attaching too great a weight to the nonprofit, educational status of Duke, and effectively suppressing the fact that Duke's acts appeared to be in accordance with its business objectives. It instructed the district court to significantly narrow its conception of the experimental use defense, focus not on the non-profit status of Duke but on the business Duke was involved in, and ascertain whether the experiments carried out in the FEL lab after Madey's departure were solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.<sup>45</sup>

For nearly two centuries university researchers were protected from patent infringement suits by the experimental purpose doctrine. In essence, *Madey* announced that the exception would no longer apply.<sup>46</sup>

#### *D. Integra Lifesciences I, Ltd. v. Merck KGaA*

One year after its decision in *Madey*, the Federal Circuit cut back the district courts' broad interpretations of § 271(e)(1). In *Integra Lifesciences I, Ltd. v. Merck KGaA*, it held that Hatch-Waxman's safe harbor was merely "meant to reverse the effect of *Roche* under *limited* circumstances, not to deprive entire categories of inventions of patent protection."<sup>47</sup>

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44. *Id.*

45. *Id.* at 1362-63. This, nonetheless, might not be the end of the story, as Judge Newman in her dissenting opinion in *Integra* argued:

[*Madey*] concerned the use of a patented laser device for the purpose for which it was made, not research into understanding or improving the design or operation of the machine. The facts of *Madey v. Duke* do not invoke the common law research exemption, despite the broad statement in that opinion. I do not disagree with that decision on its facts; I disagree only with its sweeping dictum, and its failure to distinguish between investigation *into* patented things, as has always been permitted, and investigation *using* patented things, as has never been permitted.

*Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d at 878, n.10 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part) (emphasis added).

46. It should be noted that the Federal Circuit did not throw out the experimental purpose doctrine completely: "the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, and in *Roche*." *Madey*, 307 F.3d at 1361 (citations omitted).

47. 331 F.3d at 867 (emphasis added).

At issue in *Integra* was a research project undertaken by Dr. Cheresh, a scientist at the Scripps Research Institute (Scripps).<sup>48</sup> Merck hired Dr. Cheresh to identify potential drug candidates that would halt tumor growth by inhibiting the formation of blood vessels which provide vital nutrients to rapidly dividing tumor cells. Dr. Cheresh's research showed that one drug, cyclic peptide EMD 66203, displayed promise. Consequently, Merck entered into an agreement with Scripps to fund the necessary experiments to satisfy the biological bases and FDA requirements for the implementation of clinical trials with EMD 66203 or a derivative of it. The agreement contemplated commencing clinical trials with a drug candidate within three years. In 1997, the Scripps research team chose EMD 121974, a derivative of EMD 66203, as the best candidate for clinical development.<sup>49</sup>

Integra, which owned five patents related to a short tri-peptide segment of fibronectin (the "RGD peptide"), learned of the Scripps-Merck agreement. Believing the Scripps research was a commercial project that infringed upon its RGD-related patents, Integra offered Merck licenses to its patents. After Merck declined, Integra sued Merck, Scripps, and Dr. Cheresh. Merck responded by arguing that its work with Scripps was protected by the safe harbor provided by 35 U.S.C. § 271(e)(1). Merck also argued that Integra's patents were invalid.<sup>50</sup>

The district court agreed with Merck on one issue; it held that one of Integra's patents was anticipated by a 1984 NATURE article.<sup>51</sup> However, it refused to acknowledge that the defendants' infringing activities were within the protection of the safe harbor afforded by § 271(e)(1).<sup>52</sup> At trial, the jury found Merck liable for infringing the remaining four of Integra's patents.<sup>53</sup> On appeal, Merck argued that the district court erred in interpreting § 271(e)(1).<sup>54</sup> The Federal Circuit disagreed.<sup>55</sup>

As in *Madey*, the Federal Circuit could have ruled against the accused infringer based on rules set down in previous decisions. As in *Madey*, however, the court adopted a different line of reasoning. It held that Hatch-Waxman's safe harbor does not cover pre-clinical activities. To qualify for the exemption, an otherwise infringing activity must rea-

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48. Scripps is "one of the country's largest, private, non-profit research organizations". *TSRI—About TSRI*, at <http://www.scripps.edu/intro/intro.html> (last visited Nov. 29, 2004).

49. *Integra*, 331 F.3d at 862-63.

50. *Id.* at 863.

51. *Id.* at 863-64.

52. *Id.* at 863.

53. *Id.*

54. *Id.* at 864.

55. *Id.* at 862.

sonably relate to the development and submission of information for FDA's "safety and effectiveness" approval processes.<sup>56</sup>

While the court admitted that the term "reasonably" permitted some activities that do not directly produce FDA information to qualify under § 271(e)(1), it noted that the context of Hatch-Waxman keys its use to facilitating expedited approval of generics.<sup>57</sup> Thus, the court stated, extending the safe harbor protection of § 271(e)(1) to embrace new drug development activities would ignore § 271(e)(1)'s language and context and would not confine the scope of § 271(e)(1) to a *de minimis* encroachment on the rights of the patentee.<sup>58</sup>

The court reasoned that because the FDA had no interest in hunting for drugs that might not undergo clinical testing, "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but general biomedical research to identify new pharmaceutical compounds."<sup>59</sup> Consequently, the court found that the Scripps work sponsored by Merck was beyond the scope of § 271(e)(1).<sup>60</sup>

While the *Integra* decision did not directly address the common law experimental purpose doctrine, its holding effectively shut down the loophole created by the district courts' broad interpretations of the statutory exception created in § 271(e)(1).<sup>61</sup>

## II. UNIVERSITIES AND THE BIOTECHNOLOGY INDUSTRY— A REALITY CHECK

A substantial proportion of the biomedical research conducted in the United States is conducted by universities like Duke or non-profit institutions such as the Scripps Research Institute. The combination of *Madey* and *Integra* suggests that in the future neither the common law experimental purpose doctrine nor the statutory experimental exception under § 271(e)(1) will be a useful defense for universities in patent infringement suits. To evaluate the potential impact of these two cases on biomedical research, this Part surveys the involvement of universities in the biotechnology industry and analyzes past patent infringement battles between universities and industry.

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56. *Id.* at 866.

57. *Id.* at 866–67.

58. *Id.* at 867.

59. *Id.* at 866.

60. *Id.*

61. It should also be noted that even though the *Integra* decision was not based on common law experiment purpose doctrine, the majority reaffirmed its holding in *Madey*. *Id.* at 863–64, n.2.

### A. Entrepreneurial Universities and Professors

In 1980 Congress enacted the Bayh-Dole Act<sup>62</sup> which afforded universities the right to patent the results of government-funded research. Since the Act's enactment, American universities have accumulated numerous patents. According to a 2000 survey conducted by the Association of University Technology Managers (AUTM), prior to Bayh-Dole fewer than 250 U.S. patents were issued to American universities each year.<sup>63</sup> Since 1993, universities have annually obtained, on average, more than 1,600 U.S. patents.<sup>64</sup> In addition, from 1991 to 1999 there was a 198% increase in new U.S. patent applications.<sup>65</sup> For fiscal year 2002, 7,741 new U.S. patent applications were filed by 216 institutions and 3,673 U.S. patents were issued to 219 institutions.<sup>66</sup>

Since the enactment of Bayh-Dole, universities have also been able to collect a significant amount of royalties from their patents.<sup>67</sup> There are now more than 200 universities engaged in technology transfer, eight times more than in 1980.<sup>68</sup> In addition, from 1991 to 1999, there was a 133% increase in the number of licenses issued to U.S. universities.<sup>69</sup>

One of the best known examples of a patent that generated large revenues for a U.S. university is the Cohen-Boyer patent.<sup>70</sup> The Cohen-Boyer patent was owned by Stanford University and the University of California.<sup>71</sup> Through non-exclusive licenses, Stanford and the University of California were able to collect about two hundred million dollars.<sup>72</sup>

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62. Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

63. Ass'n. Univ. Tech. Managers, *Surveys—Bayh-Dole Act*, available at <http://www.autm.net/pubs/survey/facts.html> (last visited Nov. 22, 2004) (subsequently password protected) [hereinafter *Surveys—Bayh-Dole Act*].

64. *Id.*

65. *Id.*

66. *AUTM Licensing Survey: FY 2002*, available at [http://www.autm.net/index\\_n4.html](http://www.autm.net/index_n4.html) (last visited Nov. 29, 2004) (subsequently password protected) [hereinafter *Licensing Survey: FY 2002*].

67. See generally Francesco Fiondella, *Innovation's Reward*, THE SCIENTIST, Mar. 1, 2004, at 41 (Fiondella's data shows that top research universities receive millions of dollars from licensing their patents. The institution that received the most amount of income from licensing in 2002 was Columbia University. Columbia collected \$168.1 million in 2002. This is equal to 41.3% of its total research expenditure for 2002).

68. *Surveys—Bayh-Dole Act*, supra note 63.

69. *Id.*

70. See, e.g., Rebecca Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1710 (1996).

71. U.S. Patent No. 4,237,224 (issued Dec. 2, 1980). The Cohen-Boyer patent covered one of the most widely used techniques in biology, recombinant DNA technology.

72. See Ken Howard, News, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 NATURE BIOTECHNOLOGY 955 (2003).

Stanford and the University of California are not the only research universities actively engaged in licensing. An AUTM survey reported that for 2002, the gross licensing income received by 218 institutions was \$1.267 billion and the royalties on product sales for 212 institutions amounted to \$1.005 billion<sup>73</sup>. Licensing of innovations by academic institutions in 1999 alone added about \$40 billion to the U.S. economy and supported 260,000 jobs.<sup>74</sup>

Professors, like universities, are beneficiaries of patents. Many professors are deeply involved in the biotechnology industry, acting as directors or scientific advisors of biotechnology companies, or founding their own biotechnology companies. For example, many well-established biologists, including Nobel laureates, are famous for the companies they founded.<sup>75</sup>

The involvement of universities and professors in the biotechnology industry and the significant amount of money they have obtained in return suggests that many of their research activities are no longer undertaken for pure scientific inquiry. Their research has commercial implications. As the *Madey* court correctly recognized, universities and professors are commercial entities.<sup>76</sup> Therefore, if research results in patent infringement, it should not be automatically exempted under the experimental purpose doctrine just because it occurred at a non-profit or educational institution. Because the line between the academic research carried out on university campuses and the “research and development” carried out by for-profit corporations has blurred, if not totally disappeared, the playground should be level. Universities and biotechnology companies should be held to the same standard.

### B. *Litigious Universities*

Universities are sophisticated players in biomedical research. Not only are they actively involved in patent applications and licensing, they are also diligent about protecting their patent rights. For example, universities are very aggressive in going after biotechnology and pharmaceutical companies if they believe a company is infringing a

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73. *Licensing Survey: FY 2002*, *supra* note 66.

74. *Surveys—Bayh-Dole Act*, *supra* note 63.

75. *See, e.g.*, Carolina Braunschweig, *BioVentures Triples Previous Fund*, PRIVATE EQUITY WK., Sept. 8, 2003 (reporting that Walter Gilbert, a Nobel laureate and professor at Harvard, is the founder of six biotechnology companies); Faith Keenan, *Biotech's Hope isn't Just DNA Anymore*, BUSINESS WK., Mar. 10, 2003, at 72 (reporting that Nobel laureate Phillip A. Sharp, a professor at MIT, co-founded Alnylam Pharmaceuticals (Cambridge, MA)); <http://www.biogen.com/site/010.html> (last visited April 9, 2004) (recording that Sharp, together with Gilbert, helped co-found biotech giant Biogen).

76. 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

patent they hold. Sometimes, they are successful. For instance, when Johns Hopkins University sued Cellpro for infringing its patent on monoclonal antibodies, a jury awarded it \$2.3 million dollars in compensatory damages.<sup>77</sup> In addition, since the district court found Cellpro to have infringed willfully, it imposed treble damages.<sup>78</sup> In another example, the University of California received a \$200 million settlement in response to a patent infringement suit it filed against Genentech.<sup>79</sup>

Universities, however, are not always successful when they go after biotechnology and pharmaceutical companies. For example, the University of Rochester unsuccessfully sued Pfizer and several other pharmaceutical companies for infringement of its patent on the Cox-2 gene.<sup>80</sup> Cox-2 is the target through which the blockbuster drugs Vioxx and Celebrex work. The university sought ten percent of Pfizer's annual three billion dollars in sales of Celebrex in damages.<sup>81</sup> In another lawsuit, the University of California unsuccessfully sued pharmaceutical giant Eli Lilly for patent infringement.<sup>82</sup> The patents at issue in the Eli Lilly suit covered the recombinant plasmids and microorganisms that produce human insulin.<sup>83</sup> In both cases the district courts ruled that the universities' patents were invalid for failure to comply with the statutory written description requirement.<sup>84</sup>

Sometimes, universities have been too aggressive in their tactics and have provoked preemptive strikes from the biotechnology industry. For example, Columbia University owned three patents that covered gene-splicing technology. All of them were set to expire in 2000.<sup>85</sup> Columbia enlisted its alumni to lobby Congress to extend the patents. In addition, it

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77. See *John Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998).

78. The Federal Circuit affirmed the damages award. *Id.* at 1365.

79. Bernadette Tansey, *Biotech Firm's Image on Trial/Genentech Enters Damages Phases*, S.F. CHRON., June 16, 2002, at G1.

80. *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003).

81. Michael J. Shuster et al., *Protecting Rights to Early-stage Technology*, 21 NATURE BIOTECHNOLOGY 701, 702 (2003) (noting that if the university won, it could also sue Merck for royalties on its \$2.5 billion annual sales of Vioxx).

82. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, No. MDL DKT. 912, IP-92-0224-C-D/G, 1995 WL 735547 (S.D. Ind. 1995).

83. See Linda Williams, *UC Regents Sue Lilly In Dispute Over Biotech Patent For Insulin*, L.A. TIMES, Feb. 8, 1990, at D1 ("Lilly, one of the largest U.S. pharmaceutical companies, controls 80% of the U.S. insulin market with two products. It markets insulin derived from animals under the name Iletin but sells far more of the genetically engineered insulin sold under the Humulin name. Some analysts estimate 1989 sales of Humulin at \$295 million, compared to \$160 million for Iletin.")

84. See *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); *Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

85. Howard, *supra* note 72, at 955.

filed and eventually was granted, “submarine” patents.<sup>86</sup> Biotechnology companies, including Biogen, Genzyme, and Abbott Bioresearch Center, however, struck back and sued Columbia, accusing it of engaging in an illegitimate effort to create a “patent monopoly.”<sup>87</sup> Amgen and Genentech also filed similar lawsuits.<sup>88</sup>

### *C. Universities Are Not Victims—An Empirical Study*

Some legal commentators have expressed concern about the effect of a narrow interpretation of the experimental purpose doctrine on research universities.<sup>89</sup> They worry that academic vigor will be suppressed and that researchers will not pursue certain projects out of the fear of being held liable for patent infringement. But few of *Madey* and *Integra*’s critics have provided empirical data to back up such a claim.

In the following paragraphs this Note provides empirical data which suggest that universities have not and are not being sued for patent infringement by the biotechnology industry. Table 1 summarizes the results of a survey of the patent cases involving universities that came before the Federal Circuit between 1983 and September of 2004.<sup>90</sup>

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86. U.S. Patent No. 6,455,275 (issued Sep. 3, 2002). A patent application may have a long examination period due to delays by the Patent and Trademark Office and/or from continuation applications. Patents that remain “submerged” during a long *ex parte* examination process and then “surface” upon the grant of the patent have been labeled “submarine” patents. A holder of a “submarine” patent may be able to demand high royalties from non-patent holders who invested and used the technology not knowing that patent would later be granted. See 4A Chisum, *supra* note 1, § 13.05(1) (2004).

87. Howard, *supra* note 72, at 955.

88. *Id.*

89. See Groombridge & Calabro, *supra* note 7, at 463; Saunders, *supra* note 7, 262; see also Eisenberg, *supra* note 7, at 1019; Derzko, *supra* note 7, at 389.

90. This survey was conducted in September 2004 using the Westlaw case law database of the Court of Appeals of the Federal Circuit. The survey retrieved all the cases with at least one university as a party by using the key word “university” to search the titles of the cases in the database. While this approach will miss cases that involve universities and colleges that do not have the word “university” in their names, such as Massachusetts Institute of Technology, this survey is not intended to be a comprehensive study. Rather, this approach was intended to generate a set of representative cases. The search fetched a total of 67 cases, spanning the period from 1983 to September of 2004. The cases were then individually reviewed to remove cases unrelated to patent law. If the case was pending before the Federal Circuit or was disposed without opinion, the reports from lower courts, if available, were reviewed. This generated a list of 33 patent law cases where at least one party was a university.

TABLE I  
SUMMARY OF PATENT CASES WHERE A UNIVERSITY WAS A PARTY

Cause of Action	Infringement	Declaration Judgment for Non- infringement	Inventorship /Ownership	Interference	Others
Plaintiff	19	0	3	0	2
Defendant	1	4	2	1	1

The numbers shown in Table 1 are the number of cases where a university is either a plaintiff or a defendant. The survey reveals that it is rare for a university to be sued for patent infringement. Of the twenty patent infringement cases that came before the Federal Circuit between 1983 and September of 2004, in nineteen cases universities were the plaintiffs. The only case in which a university was sued for patent infringement was *Madey* in which the plaintiff was not an industrial entity, but rather a disgruntled former faculty member.<sup>91</sup> Thus, in the 20 patent infringement cases that were heard by the Federal Circuit in its first twenty-one years of existence, a university was not once sued by industry for patent infringement. In fact, the only instances where universities were sued by the biotechnology industry were when corporations sought declaratory judgments of non-infringement.

Certainly, the survey presented here is only a rough estimation. It only includes cases that ended up on the Federal Circuit's docket. It overlooks cases where universities were sued for patent infringement but never appealed to the Federal Circuit. The survey, however, at least provides some empirical support for the proposition that universities were not and are not being threatened by biotechnology industry through patent infringement suits. An intensive review of the literature on the subject also reveals no such cases cited.

### III. AN ECONOMIC ANALYSIS OF THE EXPERIMENTAL PURPOSE DOCTRINE

As the survey presented in Part II suggested, universities are not being threatened by patent litigation initiated by corporations. On the contrary, it is the biotechnology industry that is on the defense. Yet, some commentators continue to worry that academic research will be inhibited

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91. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1351-53 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).



without a broad interpretation of the experimental purpose doctrine. This Part provides an economic argument as to why this will not be the case.

One commentator worried that small universities without substantial resources like the University of California or Johns Hopkins might not be able to withstand an expensive patent infringement suit.<sup>92</sup> This argument, however, can be turned around: because of the daunting cost of patent litigation<sup>93</sup> it is very unlikely anyone, including biotechnology and pharmaceutical companies, would sue anyone, including universities, if there was not a significant commercial value in the patents and infringing activities. Therefore, we can analyze the economic realities of patent infringement suits brought against universities by looking at the size of the universities and the commercial value of the infringing activities.

For example, suppose there is a biotechnology company that patented a highly used research tool and developed a kit based on the patent. Also assume that although the company markets the kit to research laboratories, everyone who uses the research tool uses it without obtaining a license or buying the kit.

If the university is large, like the University of California, many labs will engage in the infringing activities. Consequently, the company would lose a large amount of royalty income due to the infringing activities. In such case, if the university's infringing activities are exempted by experimental purpose doctrine, the patent would lose significant value. The company would suffer a loss and other companies would lose some of their incentive to develop new research tools. Therefore the university should not be exempted. Furthermore, as a large university, the university has the resources to defend a patent infringement suit.

Take *Integra*<sup>94</sup> as a real world example. The research at issue was funded by Merck, one of the world's pharmaceutical giants. If Merck had not funded Dr. Cheresch's work, it is unlikely that *Integra* would have sued Scripps. The lawsuit occurred because Merck not only stood to profit substantially from the infringing activities, but also because Merck had the resources to pay a large damage award.

Returning to the hypothetical, if the university is small, there will only be a few labs infringing the patent. The infringement will be minor, and the damage award will be small if the patent owner wins an infringement suit. Thus, while a small university may not have enough resources to defend patent infringement suit, a patent owner does not

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92. See Eyal H. Barash, Note, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. REV. 667, 697 (1997).

93. See Megan Barnett, *Patents Pending*, U.S. NEWS & WORLD REP., June 10, 2002, at 33-34 ("Patent lawsuits typically cost each party \$1 million, and suits costing \$4 million to \$10 million are not unheard of.")

94. 331 F.3d 860 (Fed. Cir. 2003).

have the monetary incentive to go after it. Even if a patent owner really wanted to make a statement by suing a small university, it likely the parties would settle instead of spending millions of dollars to fight it out in court.

The above hypothetical demonstrates that if universities, small or large, infringe a patent, there is no economic reason to exempt such activities under the experimental purpose doctrine. It also explains why patent litigation does not pose a serious threat to academic research.

Companies will hesitate to go after universities for non-economic reasons as well. For instance, in a jury trial that pits a big pharmaceutical company against a well respected university, it is doubtful that the pharmaceutical company will be optimistic about having a sympathetic jury. Similarly, companies might avoid suing universities for fear of negative publicity. For example, when the Swiss pharmaceutical company Hoffmann-LaRoche initiated a lawsuit against Promega to protect its Taq polymerase<sup>95</sup> patent, it identified about two hundreds basic researchers who were allegedly infringing its patent.<sup>96</sup> Those researchers, however, were not charged with infringement. In fact, the company had no interest in suing them.<sup>97</sup>

This above analysis is also supported by the survey presented in Part II.C. Indeed, we have not observed all-out patent infringement suits against universities. As Professor Eisenberg noted when commenting on *Madey*:

As universities shed their noncommercial innocence to reach deeper into the pockets of commercial firms, one might expect to see firms strike back with their own infringement claims, urging courts to reject the experimental use defense as a nostalgic fantasy.

But this is not what happened. Instead, the experimental use defense was taken out in an inside job, a casualty of an intra-academic squabble over control resources.<sup>98</sup>

Theoretically research universities could be vulnerable prey of aggressive patent owners, but the reality of patent infringement litigation renders this worry remote. It is most likely that it will be those research universities with deep pockets whom the industry-based patent owners

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95. The enzyme used in polymerase chain reaction (PCR).

96. Marcia Barinaga, *Scientists Named in PCR Suit*, 268 *SCIENCE* 1273 (1995).

97. *Id.* at 1274; *see also Roche-Promega Litigation Still Unsettled*, 22 *BIOTECHNOLOGY L. REP.* 406 (2003).

98. Eisenberg, *supra* note 7, at 1018.

will go after. And if there is a high stakes patent involved, why should universities be allowed to infringe without paying the consequences?<sup>99</sup>

### CONCLUSION

Universities should abide by the same rules of patent law as the biotechnology industry. Universities are major beneficiaries of the Bayh-Dole Act and have been collecting royalties on their patents from industry. It is fair to ask universities to reciprocate—to pay royalties to for-profit biotechnology companies on patents they obtained through their mostly privately funded endeavors.

While some commentators argue for a broader interpretation of the experimental purpose doctrine,<sup>100</sup> this approach is not advisable since granting universities a carte blanche exception will lead to inequity in patent law; universities and non-profit research organizations could infringe patents, for-profit companies could not. Moreover, to a certain extent such an exception would be a disguised form of taxing commercial entities to subsidize private universities. Thus, a broad exception could be viewed as inconsistent with the policies underlying of patent law.<sup>101</sup>

The nature of research universities is changing. More than ever universities are major players in commercializing research breakthroughs. Giving them advantages in patent infringement suits discriminates against industrial effort. Large research universities are sophisticated players in biotechnology industry and frequently are aggressive patent owners. They have both the resources and the expertise to engage in patent litigation.

Because litigation costs are very high, a narrow application of experimental purpose doctrine merely strengthens patent protection. It forces universities to form research alliances or to bargain with the companies *ex ante* in order to reach cross-licensing agreements. Therefore, in reality it will not be a battle between David and Goliath, but an even match between Goliaths. If, however, research universities begin to

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99. If the university is a public school, allowing it to defend its actions based on the experimental purpose doctrine might even raise constitutional concerns. *See generally* 5 Chisum, *supra* note 1 § 16.06 (2004).

100. *See* Ned A. Israelsen, *Making, Using, Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM. INTELL. PROP. L. ASS'N. Q.J. 457, 475 (1989); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 218-25 (1987); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617 (1985).

101. *See* Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991)(presenting a powerful argument in favor of narrower interpretation of experimental purpose doctrine).

suffer under an onslaught of patent infringement suits, Congress can always step in and legislatively broaden the experimental purpose doctrine.

In summary, the distinction between academic and commercial entities, at least in respect to biomedical research, is fading. The equity and the reality of patent litigation are in favor of a narrow interpretation of the experimental purpose doctrine. The Federal Circuit decided *Madey* and *Integra* correctly. *Madey* and *Integra* made the treatment of patent infringement by academic and commercial entities uniform and balanced the interests of the holders and users of patents by strengthening patent protection.