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## Note

# Toward Facilitating Access to Patented Research Tools

Wendy Thai\*

### INTRODUCTION

The scope and propriety of the experimental use exemption to patent infringement liability have become a controversial topic among both the legal and scientific community. Although the common law exemption has existed for almost 200 years, its applicability to academic research remained untested until *Madey v. Duke University*.<sup>1</sup> In *Madey*, the Court of Appeals for the Federal Circuit rejected a categorical exemption for university research activities, holding that the experimental use exemption is not applicable if the alleged infringing act furthers the university's legitimate business and is not solely "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."<sup>2</sup> This decision was a rude awakening for the scientific community, which, for more than two decades, had assumed immunity from patent infringement liability under this common law exemption.<sup>3</sup> In the only patent infringement case involving a university, the court had held that the defendant was not liable for contributory infringement as the use of infringing machines by a university was experimental and thus, did not amount to infringement.<sup>4</sup> Even

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1. *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

2. *Id.* at 1362.

3. See Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018 (2003); see also S. Peter Ludwig & Jason C. Chumney, *No Room for Experiment: the Federal Circuit's Narrow Construction of the Experimental Use Defense*, 21 NATURE BIOTECHNOLOGY 453 (2003).

4. *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935), *rev'd*

as late as 1985, “[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function.”<sup>5</sup> Yet today, in light of the increasing presence of universities in the intellectual property arena, many would deny just that. *Madey v. Duke University* and the surrounding controversy is a case in point.

The *Madey* case stemmed from a dispute between John Madey, inventor of the first free electron laser (FEL), and Duke University over management of the FEL research laboratory at Duke and access to equipments incorporating the FEL technology.<sup>6</sup> When negotiations over control of the laboratory reached an impasse, John Madey resigned from the faculty at Duke and later brought patent infringement charges for continued exploitation of the FEL technology without his consent.<sup>7</sup> Duke asserted the common law experimental use exemption in its defense, but this was ultimately rejected by the Federal Circuit on the ground that university research, though arguably having no commercial application, furthers the legitimate business objectives of universities and thus does not qualify for the “very narrow and strictly limited” experimental use exemption.<sup>8</sup>

Although it is difficult to justify a different outcome under the particular facts of *Madey*,<sup>9</sup> the “narrow and strictly limited” exemption set forth by the Federal Circuit has been met with much controversy. The *Madey* court makes clear that universities wanting to avoid the risk of incurring patent infringement liability must, like everyone else, obtain the consent of patent holders prior to using patented technologies in their research. Critics characterized the decision as “disastrous,”<sup>10</sup> and one that “transforms the academic science

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on other grounds, 87 F.2d 35 (10th Cir. 1936).

5. Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 633 (1985).

6. *Madey*, 307 F.3d at 1352-53; see also Eliot Marshall, *Physicist Sues Duke Over Control of Lab*, 278 SCIENCE 1393 (1997).

7. *Madey*, 307 F.3d at 1352-53.

8. *Id.* at 1362-63.

9. Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 85 (2004) (discussing the facts of the *Madey* case and stating that “a judicial exemption of such research as noncommercial experimental use would have gutted the core grant of exclusivity supposedly provided by the patent”).

10. David Malakoff, *Universities Ask Supreme Court to Reverse Patent Ruling*, 299 SCIENCE 26, 27 (2003) (quoting Sheldon Steinbach, general

landscape in a horribly perverse way.”<sup>11</sup> On the other hand, supporters contend that it serves to affirm the rights of the patent holder and is consistent with precedent and the underlying premise of patent law to promote scientific progress.<sup>12</sup> They view the decision as one that will hold universities accountable for their commercial activities.<sup>13</sup> The modern university, with its technology transfer office, patent portfolios, and corporate-sponsored research projects, is increasingly taking on the role of a market participant and shedding its traditional role as a disinterested steward of knowledge.<sup>14</sup> Viewed in this context, *Madey* undeniably appeals to one’s sense of justice and fair play.

In practice, however, and particularly as applied to biotechnology and biomedical research, a narrow and strictly limited exemption confers little practical benefit to patent holders at the expense of imposing detrimental obstacles to university research. Patent law places the responsibility of enforcing patents on patent holders, but detecting infringement in university research activity can be a challenge for patent holders who have no effective means to police the use of technologies in university laboratories.<sup>15</sup> Even when infringing activity is known, patent holders have tended to be reluctant to

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counsel of the American Council on Education in Washington, D.C.).

11. *Id.* at 26 (quoting David Korn of the Association of American Medical Colleges in Washington, D.C.).

12. See Theodore B. Olson et al., Brief for the United States as Amicus Curiae, *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003), *reprinted in* 22 BIOTECHNOLOGY L. REP. 511, 515 [hereinafter Brief] (“When the public is permitted to engage in the unlicensed use of patented inventions without incurring liability for infringement, even with respect to ‘experimental’ uses that may offer other scientific benefits, the incentives provided by the patent laws are diminished and the nature of the patent ‘bargain’ altered.”).

13. See, e.g., David B. Resnik, *Patents and the Research Exemption*, 299 SCIENCE 821 (2003).

14. *Id.* at 821; Eisenberg, *supra* note 3, at 1018-19; Ludwig & Chumney, *supra* note 3, at 453.

15. See Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property Right*, 94 COLUM. L. REV. 2655, 2657-58 (1994) (discussing the application of the Coase Theorem to inventor/infringer interactions and stating that in the intellectual property rights context, “there is no smoky soot or wandering cattle to serve as an unambiguous marker” of infringement); see also Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1071-72 (1989) [hereinafter Eisenberg, *Patents and the Progress of Science*] (“Making and using a patented invention within a research laboratory is not very conspicuous and may never come to the attention of the patent holder.”).

enforce their patents against universities as the prospective gains do not justify the risk of having their patents invalidated or the scope of their patents narrowed in an infringement suit.<sup>16</sup> To the extent that this is true, a narrow experimental use exemption may have little impact on the patent holder's decision to assert her patent against university infringers, and thus confers little tangible benefits. For university researchers, on the other hand, the impact is less benign. Recent judicial and federal patent policies have led to a proliferation of patents in the biomedical field that increasingly cover upstream technologies used as tools of laboratory research.<sup>17</sup> In response, university researchers have adopted working solutions, including outright patent infringement, to circumvent the delay and high transaction costs associated with obtaining access to patented technologies.<sup>18</sup> But patent infringement is a risky working solution in a post-*Madey* era. Without the law on their side, the fates of universities are at the discretion and good grace of patent holders whose interests are increasingly antithetical to that of universities. In sum, the current law confers little tangible benefits to patent holders, while placing university researchers between the *Charybdis* of uncertainty in relying on the forbearance of patent holders and the *Scylla* of bearing the costs and delays associated with having to obtain licenses *ex ante*.

This article sets out a method for facilitating access to patented research tools so as to maximize the benefit to patent holders and university researchers alike. The method includes a self-reporting mechanism by which a university user discloses the use of patented research tools when a patent application is filed covering the results of that research. This disclosure requirement serves to notify patent holders that their patented technologies have been used, and by requiring disclosure at the time a patent application is filed, universities are held accountable, as are other market participants, for their commercial activities. The method also includes a predetermined research fee associated with each research tool

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16. John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021 (2003) (stating "small prospective gains from a lawsuit were not worth the legal fees, the risk of the patent being narrowed or invalidated, and the bad publicity from suing a university").

17. See *id.*; see also Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

18. Walsh et al., *supra* note 16.

patent to be applied to university users. This research fee allows the patent holder to name her price while serving to notify a prospective university user of the cost of a selected research tool, thus protecting university from disgorging. In essence, the proposed model functions as a shortcut to facilitate access to patented research tools and thereby promotes efficiency in research by circumventing the need to obtain consent *ex ante*.

The first part of this paper will be a discussion of the relevant aspects of U.S. patent laws. This is followed by a brief description of the patent environment in biotechnology and the issues related to gaining access to patented research tools. Next, the paper will include a discussion of the distinction between liability and property rules, as well as compulsory licensing models that have been proposed in the legal literature. Finally, this article will describe a possible solution that involves adoption of a self-disclosure requirement and a predetermined research fee for use of patented research tools by university researchers.

#### I. PATENT AND PATENT INFRINGEMENT LAWS GENERALLY

The U.S. Constitution grants Congress the power to promote the “Progress of Science” by giving “Inventors the exclusive Right to their . . . Discoveries.”<sup>19</sup> Thus, federal patent law gives the holder of a patent the right to exclude others from making, using, offering for sale or selling the patented technology.<sup>20</sup> The right to exclude is not a natural right but rather one conferred by law and given only if statutory requirements are met. To be patentable, an invention must be of a statutorily prescribed subject matter;<sup>21</sup> it must also meet the statutory requirements of utility,<sup>22</sup> novelty,<sup>23</sup> and non-obviousness.<sup>24</sup> To obtain a patent, the inventor must timely file a patent application<sup>25</sup> that adequately discloses and claims the invention to be patented.<sup>26</sup> An adequate disclosure is one that

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19. U.S. CONST. art. I, § 8, cl. 8.

20. 35 U.S.C. § 154 (2000).

21. *Id.* § 101.

22. *Id.* § 112.

23. *Id.* § 102.

24. *Id.* § 103.

25. *Id.* § 102.

26. 35 U.S.C. § 112 (2000).

describes the invention in sufficient detail so as to enable a person of ordinary skill in the field of the invention to make and to use the invention.<sup>27</sup> In addition, the inventor also discloses in the patent specification what she believes to be the relevant field of art, the state of that art, and existing problems that the invention addresses.<sup>28</sup> During the patent procurement process, the inventor and all involved are bound by a duty of candor and good faith that requires disclosure of information material to patentability.<sup>29</sup> The duty of candor and good faith can be met by submitting an information disclosure statement that includes a list of patents, publications, applications or other information.<sup>30</sup>

Once a patent is issued, the patent holder bears the responsibility for enforcing her patent. Since a patent gives the holder the right to exclude others from practicing the invention, anyone who makes, uses, or sells a patented invention without the patent holder's consent infringes the patent.<sup>31</sup> In response, the patent holder can bring a civil patent infringement suit.<sup>32</sup> The remedies available to the patent holder include an injunction to prevent further infringement<sup>33</sup> and damages as compensation for past infringement.<sup>34</sup>

## II. PATENT INFRINGEMENT DEFENSES

A patent holder's right to recover from what otherwise would be infringing activity is not absolute. Although a patent carries a presumption of validity, an accused infringer can challenge its validity by showing a failure to satisfy the patentability requirements. A showing that the patent disclosure is not enabling, for example, would render the patent invalid and thus unenforceable.<sup>35</sup> In addition, a showing that

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27. *Id.*

28. 37 C.F.R. § 1.77 (2001); PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(a), (c) (8th ed. 2001), available at <http://www.uspto.gov/web/offices/pac/mpep/index.html>.

29. 37 C.F.R. § 1.56 (2001).

30. *Id.* §§ 1.56, 1.97-.98.

31. 35 U.S.C. § 271(a) (2000).

32. *Id.* § 281.

33. *Id.* § 283.

34. *Id.* § 284.

35. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) (holding that a claim to nucleic acid sequences that encode erythropoietin and other polypeptides having the same biological activity invalid and unenforceable on the ground that the specification did not enable one skilled

the patent holder had violated the duty of candor and good faith during the patent procurement process by intentionally engaging in fraud or inequitable conduct such as intentionally submitting false or misleading information, or misrepresenting or failing to disclose information that was material to patentability, would render the patent unenforceable under the equitable principle of unclean hands.<sup>36</sup>

A patent holder's right to recovery has also been limited by the common law experimental use exemption initially formulated in 1813. The common law exemption is presumed to be incorporated into the definition of infringement provided by section 271(a) of the 1952 Patent Act.<sup>37</sup> The experimental use exemption doctrine originated from Justice Joseph Story's opinion in *Whittemore v. Cutter*.<sup>38</sup> In *Whittemore*, Cutter was sued for infringement of a patent on a machine for making cotton and wool cards.<sup>39</sup> Having lost the suit, Cutter moved for a new trial on various grounds, one of which was an objection to the court's statement "that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right, for which an action was given by the statute."<sup>40</sup> In response, Justice Story affirmed the trial judge's charge stating: "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>41</sup> In a subsequent case, Justice Story stated "the making of a patented machine to be an offence . . . 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>42</sup>

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in the art to make and use a representative number of the claimed sequences).

36. See *Li Second Family Ltd. P'ship v. Toshiba Corp. and Toshiba Am. Elec. Components, Inc.*, 231 F.3d 1373 (Fed. Cir. 2000); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1048 (Fed.Cir.1995); *Minn. Mining and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1569 (Fed. Cir. 1992); Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARVARD J.L. & TECH. 37 (1993).

37. See Brief, *supra* note 12, at 515 (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961)).

38. *Whittemore v. Cutter*, 29 F. Cas. 1120 (1813) (No. 17,600).

39. *Id.* at 1121.

40. *Id.*

41. *Id.*

42. *Sawin v. Guild*, 21 F. Cas. 554, 555 (1813) (No. 12,391).



Early common law recognized the applicability of the exemption to the use of a patented technology “for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement . . . .”<sup>43</sup> More recent cases that further delineate the boundaries of the exemption indicate that uses that are “in keeping with the legitimate business” of the alleged infringer do not qualify for the exemption.<sup>44</sup> In these cases, the court found that either (1) there was no evidence that the alleged infringing activity was solely for experimental purposes; or (2) the alleged infringing activity had commercial purposes.

In *Pitcairn v. United States*,<sup>45</sup> for example, the government was required to compensate the inventor for use of helicopters incorporating patented rotor structures and control systems that were manufactured without a license even though the use was “for testing, evaluational, demonstrational or experimental purposes.”<sup>46</sup> In this case, there was no evidence that the use was “solely for experimental purposes.”<sup>47</sup> Experimental use was not a defense because “experiments of such nature are intended uses of the infringing aircraft . . . and are in keeping with the legitimate business of the using agency.”<sup>48</sup>

In *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*,<sup>49</sup> the Federal Circuit held that Bolar was liable for patent infringement when it used a patented drug owned by Roche in a bioequivalency test necessary to obtain U.S. Food and Drug Administration (FDA) approval for a generic version of the patented drug.<sup>50</sup> Bolar argued that its tests using a patented drug “are ‘true scientific inquiries’ to which a literal interpretation of the experimental use exception logically should extend.”<sup>51</sup> The Federal Circuit rejected this construction of the exemption, holding that the exemption was “truly narrow,” and a broad construction, according to the court, would “allow a violation of the patent laws in the guise of

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43. *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (1861) (No. 11,279).

44. *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976); *Roche Prod., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984); *Embrex v. Service Eng'g Corp.* 216 F.3d 1343 (Fed. Cir. 2000).

45. 547 F.2d 1106 (Ct. Cl. 1976).

46. *Id.* at 1125.

47. *Id.*

48. *Id.* at 1125-26.

49. 733 F.2d 858 (Fed. Cir. 1984).

50. *Id.* at 863.

51. *Id.*

‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”<sup>52</sup> “Bolar’s intended ‘experimental’ use [was] solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”<sup>53</sup> Relying on precedent, the Federal Circuit stated that “experiments . . . in keeping with the legitimate business of the . . . [alleged infringer]’ are infringements for which ‘[e]xperimental use is not a defense.”<sup>54</sup>

Similarly, in *Embrex, Inc. v. Service Engineering Corp.*,<sup>55</sup> a failed experiment conducted to design around the claims of a patent was deemed to be an infringing use.<sup>56</sup> Service Engineering Corporation (SEC) had retained two researchers to “investigate the possibility of injecting chicken embryos outside the region covered by the . . . patent claims,” but the researchers failed, and the “tests showed that . . . most injections penetrated [into the] areas covered by the . . . patent.”<sup>57</sup> The Federal Circuit rejected SEC’s argument that these experiments were protected by the experimental use exemption as the exemption was narrowly construed.<sup>58</sup> Thus, SEC was liable for patent infringement since the experiments were conducted “expressly for commercial purposes.”<sup>59</sup>

*Madey v. Duke University*<sup>60</sup> was the first case in which the applicability of the experimental use exemption to university research activities was challenged. In *Madey*, the Federal Circuit stated that the exemption would not apply if the alleged infringing use was in keeping with the university’s legitimate business and was not “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”<sup>61</sup> With respect to the “legitimate business” prong of the analysis, the court stated that research projects, arguably having no commercial applications, nonetheless further a university’s legitimate business objectives, which included “educating and enlightening students and faculty, . . . increase[ing] the status

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52. *Id.*

53. *Id.*

54. *Id.* (quoting *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976)).

55. *Embrex, Inc. v. Service Eng’g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

56. *Id.* at 1346.

57. *Id.* at 1346-47.

58. *Id.* at 1349.

59. *Id.*

60. 307 F.3d 1351 (Fed. Cir. 2002).

61. *Id.* at 1362-63.

of the institution and lur[ing] lucrative research grants, students, and faculty.”<sup>62</sup>

In addition to the common exemption, Congress has also provided a statutory exemption to infringement liability under 35 U.S.C. § 271(e) which codifies a part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.<sup>63</sup> The Hatch-Waxman Act was a response to lobbying efforts by the generic drug industry to circumvent the Federal Circuit’s decision in *Roche Products*. The generic drug industry argued that because generic drug manufacturers could not begin bio-equivalency studies with a patented drug until the patent term expires, the patent holder, in effect, gained a de facto extension of the drug’s patent term by the length of time necessary to obtain FDA approval for the generic drug.<sup>64</sup> Thus, section 271(e) provides that uses of patented drugs solely for purposes reasonably related to obtaining regulatory approval are exempt from patent infringement liability.<sup>65</sup> Most recently, the Federal Circuit has held that the exemption in section 271(e) does not encompass “exploratory research that may rationally form only a predicate for future FDA clinical tests” such as preclinical drug screening that would lead to clinical trials and the production of data for the regulatory approval process.<sup>66</sup> Section 271(e) has also been interpreted, however, to encompass the testing of medical devices.<sup>67</sup>

In enacting the Hatch-Waxman Act, it is thought that Congress did not intend to preempt the entire common law experimental use doctrine. Both the legislative history of the Act and subsequent case law from the Federal Circuit and lower courts is consistent with this proposition.<sup>68</sup> In addition,

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62. *Id.* at 1362.

63. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at scattered sections of 21 U.S.C. and 35 U.S.C.). See Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 25-27 (2001).

64. *Roche Prod., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 864. (Fed. Cir. 1984).

65. Mueller, *supra* note 63, at 25.

66. *Integra LifeSciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

67. Mueller, *supra* note 63, at 12. See *Intermedics Inc. v. Ventritex Co.* 775 F. Supp. 1269 (N.D. Cal. 1991).

68. Mueller, *supra* note 63, at 26-32.

there is evidence to support the proposition that in creating a category of activity that is exempted from infringement liability under section 271(e), Congress did not intend to preclude other types of experimental use from liability exemption.<sup>69</sup> The introduction of House Report (H.R.) 4970, the “Transgenic Animal Patent Reform Act,” by Representative Kastenmeier in 1988, has been cited in support of this proposition.<sup>70</sup> This bill would have exempted from patent infringement the breeding, use and selling of transgenic animals by farmers.<sup>71</sup> Although the bill passed the House in September 13, 1988, no further action was taken after it was referred to a Senate committee.<sup>72</sup> A more recent example is H.R. 3967, the Genomic Research and Diagnostic Accessibility Act of 2002, introduced by Representative Lynn Rivers of Michigan.<sup>73</sup> This bill would have exempted from patent infringement researchers who use patented genetic sequence information for noncommercial research purposes; it was analogous to the “fair use” doctrine in copyright law that “permits socially valuable uses without a license.”<sup>74</sup> No further action was taken after H.R. 3967 was referred to the House Judiciary Committee.<sup>75</sup>

### III. PATENTS AND BIOTECHNOLOGY

Patent laws as applied to discoveries in biotechnology have experienced significant developments in the last twenty-five years in response to rapid scientific advances. Recombinant DNA methodology, for example, was developed in 1973.<sup>76</sup> The technology allowed foreign genes to be introduced into a selected host organism, thus enabling the creation of genetically engineered organisms with new and useful traits. One such organism is a bacterium engineered by Ananda M.

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69. *Id.* at 26-27.

70. *Id.* at 27 n.132.

71. *Id.*

72. *Id.*

73. H.R. 3967, 106th Cong. (2002) at <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR03967:@@L&summ2=m&> (last visited Sept. 15, 2004).

74. See OFFICE OF LEGISLATIVE POLICY & ANALYSIS, *Legislative Updates, 107th Congress, Gene Patenting, H.R. 3966 and H.R. 3967*, at <http://olpa.od.nih.gov/legislation/107/pendinglegislation/9gene.asp> (last visited Sept. 16, 2004).

75. *Id.*

76. BERNARD R. GLICK & JACK J. PASTERNAK, *MOLECULAR BIOTECHNOLOGY, PRINCIPLES AND APPLICATIONS OF RECOMBINANT DNA 6* (2d ed. 1998).

Chakrabarty to break down components of crude oil.<sup>77</sup> The United States Patent and Trademark Office (USPTO) rejected Mr. Chakrabarty's application for patent on the engineered bacterium on the ground that living things were a product of nature and thus could not be patented.<sup>78</sup> The Supreme Court, however, upheld the patentability of the organism stating that anything made by man, whether living or otherwise, was patentable.<sup>79</sup>

Development of DNA sequencing technology also led to significant developments in patent law. Techniques for determining the sequence of DNA were first developed in 1976, and the first commercial automated DNA synthesizer was sold in 1981.<sup>80</sup> Continued advances in DNA sequencing technology resulted in determination of the genomic sequences of diverse organisms such as mosquito, mouse, rice, and human,<sup>81</sup> which in turn spurred the patenting of nucleic acids such as DNA molecules. Although the patenting of DNA molecules has also been controversial, Federal Circuit treatment of nucleic acid patents has, arguably, facilitated their patentability. For example, to satisfy the written description requirement of section 112 as interpreted by the Federal Circuit, claims covering nucleic acids must be supported by a description in the patent specification of the nucleic acid's "structure, formula, chemical name or physical properties."<sup>82</sup> A disclosure in the specification of the sequence of a polypeptide and a method for isolating nucleic acids that encode these polypeptides were deemed insufficient to satisfy the written description requirement.<sup>83</sup> Even though knowledge of a polypeptide sequence is sufficient to isolate the corresponding nucleic acid using routine methodologies, such knowledge alone is insufficient for the experimenter to predict the exact nucleic

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77. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

78. *Id.* at 306.

79. *Id.* at 310, 313.

80. GLICK & PASTERNAK, *supra* note 76.

81. See generally National Center for Biotechnology Information, *Genome Resources*, at <http://www.ncbi.nlm.nih.gov/Genomes/index.html> (last visited Sept. 16, 2004).

82. See Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155, 1174-77 (2002) (discussing the Federal Circuit's invalidation of nucleic acid claims in *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993) and *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)).

83. *Id.*

acid that would be obtained.<sup>84</sup> Similarly, public knowledge of a polypeptide sequence and methodology for isolating the corresponding nucleic acid does not render obvious a claim to a particular nucleic acid that encodes the polypeptide of interest.<sup>85</sup> The combined effect of the Federal Circuit's application of the written description and non-obviousness requirements to claims covering nucleic acids has been postulated to lead to a large number of DNA patents, though with narrow coverage.<sup>86</sup>

Advances in biotechnology and the corresponding developments in patent law have led to a proliferation of patents covering biotechnology discoveries.<sup>87</sup> From 1990 to 2000, for example, the number of patents granted by the USPTO in the field of biotechnology had risen by fifteen percent annually compared with a five percent rise in all patents.<sup>88</sup> A particular concern with the proliferation of patents covering biotechnology discoveries is the fact that these patents cover fundamental research discoveries such as disease-related genes, functional genetic elements, and transgenic animals that are necessary for further downstream research.<sup>89</sup> Such upstream patents impede downstream research and development when patent holders restrict the availability of patented research tools, demand excessive licensing fees, or impose restrictive licensing terms.<sup>90</sup> Another facet of the problem has been described as the "tragedy of the anticommons" in which the fragmentation of intellectual property rights in an innovation creates a situation in which it is difficult to obtain a complete set of licenses for research into the subject area of the innovation.<sup>91</sup> To illustrate, in a

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84. See *id.* at 1178-79 for a more extensive discussion of the biological relationship between polypeptides and nucleic acids.

85. *Id.* at 1177-79 (discussing *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993), *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), and the Federal Circuit's application of the non-obviousness standard).

86. *Id.* at 1181-82.

87. See Mueller, *supra* note 63, at 5-6.

88. ORG. FOR ECON. CO-OPERATION AND DEV., PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 22 (2004), available at <http://www.oecd.org/dataoecd/48/12/24508541.pdf>.

89. See Mueller, *supra* note 63, at 7-8 (discussing difficulties in gaining access to patents covering DNA sequences, nucleic acid vectors, and transgenic mice); see also Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (2004).

90. See Mueller, *supra* note 63, at 7-8.

91. See Heller & Eisenberg, *supra* note 17, at 699.

discussion paper on the ethics of DNA patenting, the Nuffield Council on Bioethics reported that over twenty U.S. patents were implicated in the development of a malaria vaccine: five core U.S. patents relate to the MSP-1, a protein produced by the malaria parasite; a dozen other patents relate to “add-on” technologies such as nucleic acid sequences useful in constructing a vaccine; and an additional five relate to the production of MSP-1 vaccines.<sup>92</sup> In these cases, even if the necessary technologies are available for licensing, the delay and transaction costs associated with obtaining licenses would impede downstream research.<sup>93</sup> These hurdles are further exacerbated by the universities’ lack of expertise in handling multiple licensing transactions.<sup>94</sup>

Further complicating the issue is the fact that universities have become active participants in the patent market. In 1980, to facilitate technology transfer from federally-sponsored research to the industry, the Bayh-Dole Act<sup>95</sup> and the Stevenson-Wydler Act<sup>96</sup> were passed. The Bayh-Dole Act, in

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92. NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA, 43 (July 20, 2002), available at [http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication\\_310.html](http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html); see also Heller & Eisenberg, *supra* note 17, at 699 (noting that there were more than 100 issued U.S. patents in which the term “adrenergic receptor” is found in the claim).

93. See Heller & Eisenberg, *supra* note 17, at 700; see also Malakoff, *supra* note 10, at 26 (stating that universities believe research would be hindered if scientists are forced to obtain permission from before using patented technologies); *id.* at 27 (quoting Sheldon Steinbach, general counsel of the American Council on Education as saying that it would be “disastrous” . . . if researchers have to stop and conduct expensive, time-consuming patent searches and make licensing deals every time they want to bring a new technology or technique into the lab.”); Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is this Market Failing or Emerging*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 223, 225 (Rochelle Cooper Dreyfuss et al. eds, 2001) (stating that there is a widely shared perception among scientists and university technology transfer professionals that “negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biomedical research and product development” and further that “[s]cientists report having to wait months or even years to carry out experiments while their institutions attempt to renegotiate the terms of ‘Material Transfer Agreements’ . . . database access agreements, and patent license agreements”).

94. See Heller & Eisenberg, *supra* note 17, at 700.

95. Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2000) (commonly known as the “Bayh-Dole Act”).

96. Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, § 2, 94 Stat. 2311-2320 (1980) (codified as amended at 15 U.S.C. §§ 3701-3715 (2000)).

particular, allowed universities to retain title to federally-funded research discoveries and required that universities seek patent protection for federally-funded inventions for which they elect to retain title.<sup>97</sup> As a result, the number of universities engaged in technology transfer has experienced an eight-fold increase between 1980 and 2000, accompanied by a corresponding increase in patenting and licensing activities.<sup>98</sup> In addition to their significant patenting and licensing activities, universities are also placing restrictions on the dissemination of research materials that may prove commercially valuable in downstream research.<sup>99</sup> As universities become increasingly significant participants in the intellectual property market, it becomes more difficult to justify a research exemption even in light of the burdensome transaction costs associated with gaining access to patents covering upstream technologies. Michelle Walters, for example, has argued that when an invention is patented and the university derives monetary benefits, then the experimental use exemption may be inapplicable.<sup>100</sup> The *Madey* court cited Duke University's "aggressive patent licensing program" to support rejection of a categorical experimental use exemption for university research activity.<sup>101</sup>

#### IV. PROPERTY AND LIABILITY RULES

Numerous proposals have been made to modify the

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97. See COUNCIL ON GOVERNMENTAL RELATIONS, *THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS* (1999), at <http://www.ucop.edu/ott/bayh.html>.

98. Assoc. of Univ. Tech. Managers, *Surveys – Bayh-Dole Act* (2000), at <http://www.autm.net/pubs/survey/facts.html> (reporting that (1) fewer than 250 U.S. patents were issued to universities annually prior to the Bayh-Dole Act, while more than 2,000 patents were issued annually to universities in the late 1990's, and (2) a 133 % increase in licenses between 1991 and 1999); cf. Rai & Eisenberg, *supra* note 89, at 291-92 (noting that the number of patents issued to universities annually had increased from 264 in 1979 to 2,436 in 1997 compared to the two-fold increase in all patents); Assoc. of Univ. Tech. Managers, *Surveys – Common Questions & Answers About Technology Transfer* (2000), at <http://www.autm.net/pubs/survey/qa.html> (reporting that 3,914 new licenses agreements were signed by universities in 1999, a 129 % increase from 1991).

99. See Rai & Eisenberg, *supra* note 89, at 291.

100. Michelle Walters, *De Minimis Use and Experimental Use Exceptions to Patent Infringement: A Comment on the Embrex Concurrence*, 29 AIPLA Q. J. 509, 537 (2001).

101. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1362-63, n.7 (Fed. Cir. 2002).



experimental use exemption to address the concern that patents on upstream discoveries would hinder downstream research.<sup>102</sup> Many of these advocate the adoption of a liability rule approach to facilitate access to patented research tools.<sup>103</sup> The United States patent system implements a property rule by recognizing in the patent holder a right to exclude others from her property.<sup>104</sup> The patent holder is empowered with the right to seek damages for past infringement as well as the right to injunctive relief to prevent future infringement.<sup>105</sup> Under a liability-rule system, however, a patent holder is entitled to be compensated for encroachment on her property in lieu of the right to exclude.<sup>106</sup> In addition, the amount of compensation is objectively determined by the state rather than by the parties involved.<sup>107</sup> A property rule is the method of choice in the context in which transaction costs associated with allocating property rights between the property owner and others are low relative to the costs related to determining damages and compensation after encroachment has taken place.<sup>108</sup> In contrast, a liability rule is useful when the transaction costs of bargaining are high.<sup>109</sup>

Liability rules tend to be the exception applied when the public interest in broader access to a patented invention is deemed to be more important than the private interest of the

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102. See e.g., Eisenberg, *Patents and the Progress of Science*, *supra* note 15; Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK 163 [hereinafter Eisenberg, *Patenting Research Tools*]; Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Mueller, *supra* note 63; Strandburg, *supra* note 9; David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993 (2004).

103. See e.g., Eisenberg, *Patents and the Progress of Science*, *supra* note 15; Eisenberg, *Patenting Research Tools*, *supra* note 102; Mueller, *supra* note 63; Hoffman, *supra* note 102.

104. See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1971).

105. 35 U.S.C. §§ 283, 284 (2000).

106. See Calabresi & Melamed, *supra* note 104, at 1092.

107. See *id.*

108. See *id.*

109. See *id.* at 1106 (stating “[o]ften the cost of establishing the value of an initial entitlement by negotiation is so great that even though a transfer of the entitlement would benefit all concerned, such a transfer will not occur” as justification for the need for liability rules).

patent holder.<sup>110</sup> In these cases, the patent holder is “forced to tolerate, against his will, the exploitation of his invention” by another.<sup>111</sup> This hostility towards the rights of patent holders contributes, in part, to the unpopularity of liability rule-based approaches such as compulsory licensing in the United States.<sup>112</sup>

An additional argument against a liability-rule approach in general emphasizes the difficulty in implementation, since there are no effective methods of detection and valuation.<sup>113</sup> The difficulty in detecting infringement stems from the abstract nature of intellectual property. In contrast to “[a] farmer adjacent to a cattle ranch [who] will normally have no trouble determining when cattle have trampled her crops,” in the intellectual property context, “there is no smoky soot or wandering cattle to serve as an unambiguous marker . . . . Creators very often work far away from each other, and at different times.”<sup>114</sup> Particularly illustrative are patented research tools. “[R]esearch tool[s],” as defined by the National Institutes of Health Working Group on Research Tools, encompass “the full range of resources that scientists use in the laboratory” and include “cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools . . . .”<sup>115</sup> When the use of research tools is not disclosed in some way, for example, when the tool is not incorporated into the final product or the use is not disclosed as part of a publication or patent specification, it can be difficult for the

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110. JEROME H. REICHMAN & CATHERINE HASENZAHN, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS, HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA 21 (2003), at <http://www.iprsonline.org/unctadictsd/projectoutputs.htm>.

111. *Id.*

112. See Eisenberg, *Patenting Research Tools*, *supra* note 102, at 174 (stating that if modification of the experimental use exemption to deny patent holders an injunctive remedy but permitting recovery of a reasonable royalty as damages is perceived as a compulsory licensing, it “may be opposed throughout the industry” and then suggesting that an exemption that denies a damage remedy altogether is preferable because this “would seem less like a compulsory license provision . . . although ultimately more hostile to the interests of patent holders”).

113. See Merges, *supra* note 15, at 2657-60.

114. *Id.* at 2658.

115. See Mueller, *supra* note 63, at 11 (quoting NATIONAL INSTITUTES OF HEALTH (NIH), REPORT OF THE WORKING GROUP ON RESEARCH TOOLS 3 (1998), at <http://www.nih.gov/news/researchtools/index.htm>).

patent holder to detect that use. With respect to valuation, in a liability rule-based approach, the difficulty results from the “abstract quality of the benefits” conferred by intellectual property and their “cumulative, interdependent nature,” both of which lead to disagreements as to whether and to what extent a prior work added to the subsequent one.<sup>116</sup> In addition, the uniqueness of the intellectual property contributes to the difficulty in determining value by a third party.<sup>117</sup> These difficulties can lead to undervaluation or overvaluation and result in undercompensation or overcompensation. In a property rule-based approach in which the parties are left to bargain for the value of the exchange, the heterogeneous interests and cognitive biases of the parties involved become obstacles in arriving at an agreed value for the exchange.<sup>118</sup> Cognitive biases, such as overestimating the likelihood that one’s own asset among multiple potential options would be the critical contribution or overvaluing one’s own asset while undervaluing that of others, postulated to be pervasive among scientists, could interfere with successful bargaining.<sup>119</sup>

#### V. CRAFTING AN EXPERIMENTAL USE EXEMPTION – EXISTING MODELS

Professor Janice Mueller has addressed the above concerns in her model proposing a liability rule approach for regulating access to patented research tools.<sup>120</sup> In her model, the research tool user is required to notify the patent holder of the intended use as well as any products about to be marketed that have been developed from that use.<sup>121</sup> Those failing to provide notice to the patent holder would be subject to treble damages once infringement is established.<sup>122</sup> The model employs a reach-through royalty structure to compensate the patent holder for use of a patented research tool.<sup>123</sup> The reach-through royalty structure links royalty payments to the patent holder with the commercial value of any products developed from the use of the

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116. See Merges, *supra* note 15, at 2658-59.

117. *Id.* at 2664.

118. See Eisenberg & Heller, *supra* note 17, at 701.

119. *Id.*

120. Mueller, *supra* note 63.

121. *Id.* at 58-59.

122. *Id.* at 59.

123. *Id.* at 58.

patented research tool.<sup>124</sup> The model applies to research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase.<sup>125</sup> The term “research tools” encompasses tools used in the “development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool.”<sup>126</sup> The development use model’s focus on commercial products and royalties determined from sales, profits and production costs renders it less suitable for the university research tool user if the “products” developed from that use take the form of patents. One way to adapt Professor Mueller’s model to the university setting would be to link royalty payments with patent licensing revenues rather than sales of marketed products.

Recently, Professor Katherine Strandburg has proposed another approach to crafting the experimental use exemption that relies on the distinction between “experimenting on” and “experimenting with” a patented invention.<sup>127</sup> Professor Strandburg defined “experimenting on” as “experimentation aimed at verifying, designing around, or improving upon a patented invention,”<sup>128</sup> while “[e]xperimenting with” is experimentation in which a patented invention is used . . . as a research tool.”<sup>129</sup> She proposed that “experimenting on” a patented invention should be broadly permitted without regard to the commercial or noncommercial nature of the user as the experiment has little impact on the incentive to invent.<sup>130</sup> In contrast, she proposed a limited exemption for “experimenting with” a patented research tool in which the patentee is given an initial period of complete exclusivity followed by a period of compulsory licensing.<sup>131</sup>

Noting the difficulty in applying the experimenting on/with distinction in the biotechnology context, Professor Strandburg stated that an infringing experimentation falls into the “experimenting on” category if the infringement could have been avoided in principle by more information about the

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124. *Id.*

125. *Id.*

126. Mueller, *supra* note 63, at 14.

127. Strandburg, *supra* note 9, at 88-89.

128. *Id.* at 88.

129. *Id.* at 89.

130. *Id.*

131. *Id.* at 90.

patented invention.<sup>132</sup> Yet this standard is also difficult to apply. To illustrate, Professor Strandburg applied this test to the infringing experiments in *Integra Lifesciences*.<sup>133</sup> In this case, Merck was found liable for patent infringement when its researchers conducted biochemical experiments using peptides drug candidates that fell within the generic class of peptides patented by Integra Lifesciences.<sup>134</sup> Applying the above test, Professor Strandburg concluded that the Integra experiments fell into the “experimenting on” category for several reasons. The purpose of the experiments was to learn more about the new peptides; and if the new peptides were within the scope of the more generic peptide patented, then experiments using the new peptides would have been conducted to better understand the patented invention.<sup>135</sup> However, the purpose of the Integra experiments was to develop new treatment for cancer, diabetic retinopathy and other conditions,<sup>136</sup> rather than to better understand the nature of these peptides. More specifically, Dr. David Cheresch, a researcher at Scripps, had discovered a mechanism for interfering with angiogenesis, and this discovery was of interest to Merck because inhibiting angiogenesis is a potential method of halting tumor growth.<sup>137</sup> As a result, Merck “hired Scripps and Dr. Cheresch to identify potential drug candidates that might inhibit angiogenesis,” and this led to the discovery of particular peptides that were ultimately found to infringe Integra’s patents.<sup>138</sup> Merck and Scripps then entered into an agreement to “fund the necessary experiments ‘to satisfy the biological basis and regulatory (FDA) requirements for the implementation of clinical trials’ with EMD66203;” this agreement “contemplated commencing clinical trials with a drug candidate within three years.”<sup>139</sup> Thus, Merck’s interest in the peptides stemmed from their potential usefulness as drugs and Merck’s primary purpose was to find new treatments for disease conditions. Put another way, the experimentation found to be infringing was conducted

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132. *Id.* at 148.

133. Strandburg, *supra* note 9, at 149.

134. *Integra LifeSciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

135. Strandburg, *supra* note 9, at 149.

136. *Integra Lifesciences I*, 331 F.3d at 863.

137. *Id.*

138. *Id.*

139. *Id.*

for the purpose of gaining better understanding of how tumor growth could be suppressed by inhibitors of angiogenesis, and the infringing peptides were the necessary tools in this endeavor. In sum, an experimental use exemption that relies on an experimenting on/with distinction may be difficult to apply in the biotechnology context.

#### VI. A DISCLOSURE REQUIREMENT AND A PREDETERMINED RESEARCH FEE FOR UNIVERSITY USERS?

This article sets out another approach that will provide universities with a mechanism for unfettered access to patented research tools, while at the same time facilitating recovery by the patent holder for that use. The proposed model is to be applied when the user of patented technology is a university researcher. It incorporates the definition of research tools set out by Professor Janice Mueller.<sup>140</sup> Thus, the term “research tools” refers to all patented tools used in biotechnology research that do not become physically incorporated into a product that is ultimately marketed.<sup>141</sup> In addition, only those “research tools” that are not readily available for licensing on reasonable terms, or not available via anonymous marketplace purchase, are included.<sup>142</sup> The proposed model is triggered when a university becomes a participant in the intellectual property market. Once a university becomes a market participant, the model imposes a research tool disclosure requirement on the university user. The model also requires all patent holders stipulate to a predetermined research fee to be applied to university users. The following is a discussion of the various aspects of the present model and how each addresses the concerns raised above.

##### A. THE UNIVERSITY AS A MARKET PARTICIPANT

The proposed model is based on the premise that when a university participates in the market it should be treated as all other market participants.<sup>143</sup> A university is deemed to be a *per se* market participant when it seeks patent protection for its

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140. See Mueller, *supra* note 63, at 14.

141. *Id.*

142. See *id.* at 15, 58.

143. See Walters, *supra* note 100.

research. Thus, the university's obligation to compensate the patent holder when a research tool has been used in research is triggered when the university files a patent application covering the results of that research. The university has no obligation to compensate the patent holder when the result of research is dedicated to the public by publication without patenting. Thus, in the absence of extraordinary circumstances, unless and until the university files a patent application, it incurs no liability to the patent holder as the university is presumed to be acting in the interest of furthering the public good.

In distinguishing between a university acting in the public interest and one acting as a market participant, the model holds a university accountable for its commercial activity without alleviating any undue delays and costs related to gaining access to patented research tools. The model also protects the interests of patent holders, particularly those of the holders of patents covering research tools. A broad exemption from infringement liability for university researchers would undermine the value of research tool patents as researchers tend to be "ordinary consumers" of such technologies.<sup>144</sup> The current narrow exemption from infringement liability poses obstacles to research by imposing burdensome measures to avoid the risk of liability. This approach strikes a balance between maintaining the incentive to invent and ensuring that research is not unduly hampered by patents on research tools.

#### B. RESEARCH TOOL DISCLOSURE REQUIREMENT

The model adopts a disclosure requirement similar to that in Professor Mueller's development use model.<sup>145</sup> It differs from Professor Mueller's model in that the filing of a patent application would trigger the present disclosure requirement. The disclosure requirement would impose a duty on the part of the university user to disclose the use of a patented research tool at the time a patent application is filed. This provides an efficient mechanism for apprising the patent holder that her patented research tool has been used. Self-reporting is important when infringement is difficult to detect. It is critical when research tools are not physically incorporated into a

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144. See Brief, *supra* note 12, at 518.

145. See Mueller, *supra* note 63.

marketed product or where the results obtained are patented, but the use is not disclosed in the patent. In these latter cases, the patent holder would have no effective means to detect the use. Thus, a self-reporting mechanism would ensure that a research tool user can be held accountable for that use.

The disclosure requirement is envisioned as an extension of the patent procurement process. The requirement would impose a duty on university applicants that is akin to the duty to disclose information material to patentability that is required of all applicants by the requirement for good faith and candor.<sup>146</sup> Under the research tool disclosure requirement, a university applicant would have a duty to disclose patented research tools necessary to the discovery for which the patent is sought. A research tool would be necessary when it materially affects the direction or course of the research conducted. A research tool would also be necessary when used as a control so as to give meaning and allow for interpretation of research results. As is the case with the duty to disclose information material to patentability, a failure to comply with the research tool disclosure requirement would render any patent subsequently issued to the researcher unenforceable. University researchers who choose not to respect the rights of other patent holders should be denied the same right.

The duty under the disclosure requirement would not be contingent on the validity of the research tool patent used in the research. Compliance with the disclosure requirement should not be taken as an acknowledgment by the university patentee that the patent implicated in the research is valid. The university would be free to refuse to compensate the patent holder if it deems the research tool patent invalid. The patent holder, in turn, would still be able to seek judicial redress as would be done under the existing system. This provides a mechanism by which universities could challenge patents of questionable validity.

### C. PREDETERMINED RESEARCH FEE

The disclosure requirement would be unworkable, however, without a method for limiting liability once infringement, in essence, is admitted. Thus, the model also requires that all patent applicants specify a research license fee to be applied to university users. The predetermined fee allows

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146. 37 C.F.R. § 1.56 (2001).



the patent holder to name her price while providing prospective users with notice of the cost of a patented research tool. The research fee is designated by the patentee when the research tool patent is issued, although it can be adjusted by the patent holder during the patent term. The patent holder is free to raise her price if the technology proves to be robust or lower her price if demand is low. Changes to the fee will not be applied retroactively however. Thus, the research fee is pre-determined in the sense that prospective users of patented research tools are notified of the cost of that tool. This enables the prospective user to make an informed decision to use a selected research tool or go without. It also protects the user from excessive demands from the patent holder after she has committed to a selected research tool.

Under the current law, the prospective gains from a patent infringement lawsuit against a university are often too small to justify the risk of having a patent narrowed or invalidated.<sup>147</sup> Thus, most patent holders do not recover for infringing use, choosing instead to tolerate university infringement.<sup>148</sup> This model allows the patent holder to recover for the use of her research tools without having to risk an infringement law suit. Since the patent holder has much to gain, under ordinary circumstances, one would expect the patent holder to state a reasonable price to attract the greatest possible use. This will enhance the value of the research tool and maximize recovery.

A potential pitfall in having the patent holder name her price is that sometimes the stipulated price would be prohibitively high. If so, the prospective university user has several options. First, she can select an alternative tool. If enough prospective users look elsewhere for alternative approaches, the value of the research tool patent may drop and the patent holder would be expected to adjust her price accordingly – that is, if the patent holder is willing to make her technology available to others. In this case, the present model allows the patent holder and ultimately the market to determine the value of a patented research tool. On the other hand, if selecting an alternative tool is not possible, the researcher can refuse to pay the specified fee, in which case the patent holder is free to bring suit. In essence, the model provides a “short-cut” for the prospective user to gain

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147. Walsh et al., *supra* note 16.

148. *Id.*

unfettered access to patented research tools and for the patent holder to quickly recover from her investment.

By committing to a research fee, the patent holder has not forfeited the exclusive right to market the subject of her patent. For example, the holder of a patent covering a DNA element designed to isolate operative genes from a pool of genomic DNA still retains the right to produce and market the DNA element. The research fee merely notifies the would-be university researcher of the cost for independently synthesizing and using that DNA element should she choose to. When the patent holder elects to produce and market the DNA element, the DNA element is now available for anonymous purchase and thus would be outside the ambit of the proposed model.

### CONCLUSION

Current patent laws require that university researchers wanting to avoid the risk of patent infringement liability engage in *ex ante* negotiations with patent holders for access to patented research tools. But the increasing number of patents on upstream research tools as well as the fragmentation of rights for a given innovation results in increasing transaction costs associated with gaining access to research tools. This article sets out a method for facilitating a university's access to patented research tools while enabling patent holders to recoup their investments in developing these tools. The method utilizes a research tool disclosure requirement and a predetermined research fee to facilitate university access to patented research tools and patent holder's recovery for that use. The disclosure requirement imposes on university researchers who use patented research tools a duty to disclose that use at the time of the filing of a patent application. The disclosure requirement provides notice to patent holders whose technology has been used in research. The predetermined research fee is an amount set by the research tool patent holder at the time the research tool patent is issued. It provides notice of the cost of a selected technology to would-be users and limits their liability in exchange for disclosure. The proposed model alleviates the need to obtain prior consent from patent holders, while strengthening the value of research tool patents by providing a means by which patent holders can more efficiently monitor and recover for the use of the patented research tool.