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## *Merck v. Integra*: Bailing Water Without Plugging the Hole

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## *Merck v. Integra:* Bailing Water Without Plugging the Hole

### I. INTRODUCTION

When Rochelle Dreyfuss, Pauline Newman Professor of Law at New York University School of Law, began working as a bench chemist for a pharmaceutical company in the late 1970s, there was a vigorous, free exchange of ideas, experimental results, and even novel chemical compounds between academia and industry.<sup>1</sup> This exchange was based on the Mertonian ethos, and free access to scientific advances through the public domain was the norm.<sup>2</sup> In essence, islands of private patent rights floated in a sea of pro-competitive public domain and, by default, scientific discoveries were part of that public domain.<sup>3</sup>

A very different world confronts researchers today. Universities seek and profit greatly from patents, which would have been unthinkable thirty years ago.<sup>4</sup> Pharmaceutical companies are now reluctant to share discoveries and information with universities because these are viewed as direct competitors. The vigorous public sphere of science has substantially eroded. The paradigm has radically shifted such that islands of public domain float about in a vast sea of anti-competitive patent rights.<sup>5</sup> Intellectual property is now the default.

As part of what will be shown to be a limited move back towards the previously prevailing competitive baseline, *Merck v. Integra*<sup>6</sup> served to affirm an expansive reading of the § 271(e)(1) safe-harbor created in the 1984 Hatch-Waxman Act.<sup>7</sup> In its unanimous decision penned by Justice

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1. Rochelle Dreyfuss, *Biotechnology Patents Get Special Treatment: Protecting the Public Domain of Science: Has the Time for an Experimental Defense Arrived?*, 46 ARIZ. L. REV. 457, 458 (Fall 2004) (explored in detail in PART V, *infra*).

2. *Id.* at 464.

3. *Id.* at 465. This paradigm squares well with the strong presumption against the validity of monopolies that tempered the creation of the patent system in the United States.

4. *Id.* at 464; *see also* *Bayhging for Blood or Doling Out Cash?*, Economist.com, available at [http://www.economist.com/science/PrinterFriendly.cfm?story\\_id=5327661](http://www.economist.com/science/PrinterFriendly.cfm?story_id=5327661) (discussing the pros, cons, and the recent “backlash” against the patenting of technologies by universities).

5. Rochelle Dreyfuss, *Biotechnology Patents Get Special Treatment: Protecting the Public Domain of Science: Has the Time for an Experimental Defense Arrived?*, 46 ARIZ. L. REV. 457, 465 (Fall 2004).

6. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

7. Pub. L. No. 98-417, 98 STAT. 1585 (1984) (codified as amended at 21 U.S.C. §§ 301, 355, 360cc (2003); 28 U.S.C. § 2201 (1993); 35 U.S.C. §§ 156, 271, 282 (2003)).

Scalia, the Supreme Court affirmed an expansive definition of § 271(e)(1) and continued the trend in patent law of extending protection from infringement liability in the drug sector as far as prudent. The Court missed, however, the opportunity to breathe life into the embattled and, arguably, defunct common-law research exemption.

Part II of this Comment will briefly trace the histories of the common-law research exemption and the Hatch-Waxman safe-harbor. Part III will outline *Integra v. Merck*, the Court of Appeals for the Federal Circuit (CAFC or Federal Circuit) decision that led to *Merck*. Part IV will analyze *Merck* in detail, emphasizing that decision's beneficial reversal of the CAFC's restrictive opinion in *Integra*. Part V will then address *Merck*'s missed opportunity to deal with the common-law research exemption and the treatment of research tools under § 271(e)(1), which have the potential to seriously impact the public domain in biomedical and pharmaceutical research. Part V advances possible solutions and addresses the shortcomings of each. Part VI concludes by urging Congress to action.

## II. RESEARCH EXEMPTION AND § 271(E)(1) SAFE-HARBOR

### A. Common-law Research Exemption

Just as reproduction of an expression protected by copyright constitutes copyright infringement, use of a patented invention constitutes patent infringement.<sup>8</sup> Unlike copyright law, however, no statutory fair-use exemption exists in patent law.<sup>9</sup> Only an embattled common-law exemption is available to most accused patent infringers.

In 1813, *Whittemore v. Cutter* introduced the first common-law exemption to patent infringement.<sup>10</sup> In *Whittemore*, Justice Story stated “[i]t could never have been the intention of the legislature to punish a man, who [without license] constructed such a [patent protected] machine merely for philosophical experiments . . . .”<sup>11</sup> Several subsequent cases mentioned this “research” exemption in dicta but generally found it inapplicable to the particular facts.<sup>12</sup>

The exemption narrowed continually in dicta until 2002 when the CAFC, in *Madey v. Duke*, essentially interred it. In *Madey*, the Federal

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8. 17 U.S.C. § 501(a) (2005); 35 U.S.C. § 271(a) (2005).

9. 17 U.S.C. § 107 (2005).

10. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.D. Mass. 1813).

11. *Id.*

12. Ruth E. Freeburg, Comment, *No Safe Harbor and No Experimental Use: Is it Time for Compulsory Licensing of Biotech Tools?*, 53 BUFFALO L. REV. 351, 363-64, n.75 (Winter 2005).

Circuit was confronted with Duke University's use of a patented laser in its research laboratories.<sup>13</sup> Because use of the laser was "solely for research, academic, or experimental purposes," the District Court agreed with Duke's argument that the laser's use was covered by the research exemption and thus Duke was not liable for infringement.<sup>14</sup> On appeal, however, the Federal Circuit found this formulation of the exemption to be overly broad, noting that only use of patented inventions "for amusement, to satisfy idle curiosity or for strictly philosophical inquiry" would be protected from liability.<sup>15</sup> Backed by an impeccable precedential pedigree,<sup>16</sup> the court further noted that the experimental use exemption<sup>17</sup> would not apply if the use of the invention was under the "guise of scientific inquiry," had "definite, cognizable, and not insubstantial commercial purposes,"<sup>18</sup> or had the "slightest commercial implication."<sup>19</sup> Because Duke is in the business of procuring government and private research grants, and much of its potential to attract students' tuition payments depends on its research prowess, the court ruled that the experimental use exemption was not available to Duke.<sup>20</sup> The court reasoned that teaching and research constituted two of Duke's "legitimate business objectives," making use of the laser an inexcusable infringement.<sup>21</sup>

One implication of *Madey* is that the research exemption will likely be deemed unavailable, even to a non-profit research organization whose specific research has no immediate commercial implication.<sup>22</sup> The logical

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13. *Madey v. Duke Univ.*, 307 F.3d 1351, 1353 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

14. *Id.* at 1361.

15. *Id.* at 1362 (quoting *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1348 (Fed. Cir. 2000)).

16. After Justice Story's formulation of the exemption, courts uniformly refused to exempt anyone from infringement liability, all the while insisting that the existence of the exemption was "well settled law." This reminds the author of his childhood, when his older brother would repeatedly insist that performance of some household chore, invariably assigned to the older brother, would result in some attractive benefit, only to find the performance technically lacking. *See, e.g., Hogg v. Emerson*, 52 U.S. 587, 608 (1850); *Embrex*, 216 F.3d at 1346; *Madey*, 307 F.3d at 1359-61; *Infigen, Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 981 (W.D. Wisc. 1999); *Poppenhusen v. New York Gutta Percha Comb Co.*, 19 Fed. Cas. 1059, No. 11,283 (C.C. S.D. N.Y. 1858).

17. Note that this casenote follows Judge Newman's convention of using the terms "experimental use" and "research" interchangeably.

18. *Madey*, 307 F.3d at 1362 (quoting *Roche Products, Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

19. *Embrex*, 216 F.3d at 1353 (concurring opinion).

20. *Madey*, 307 F.3d at 1362.

21. *Id.* (citing *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Cl. Ct. 1976)). Notice that *Pitcairn* involved tests with aims and implications that would clearly fall under a traditional conception of "commercial." The court truly stretched this concept in finding Duke's experiments "commercial" in *Madey*.

22. *Madey*, 307 F.3d at 1362.

result of *Madey* narrows the research exemption to the point that it has little efficacy because it virtually guarantees that courts will be able to ferret out some “commercial” application or purpose behind the defendant’s use.<sup>23</sup> One must pause to wonder where the exemption might possibly be found to apply post-*Madey*. Despite the erosion of this common law exemption and recognizing a need for protected use of patented products, Congress has provided some statutory relief to researchers in 35 U.S.C. § 271(e)(1).

### *B. Origins of § 271(e)(1) Safe-Harbor*

In order to receive regulatory approval to produce and market a prescription drug, a manufacturer must file a new drug application (NDA) with the Food and Drug Administration (FDA) proving that the drug is safe and efficacious in the treatment of disease.<sup>24</sup> The clinical trials involved in amassing this proof are extremely expensive and time-consuming.<sup>25</sup> After the patent protection period on a particular drug compound has expired, numerous companies generally enter the market and produce what are commonly known as “generic” versions.

Before 1984, these generic drug manufacturers had to go through the same regulatory process their “innovative” predecessor endured in filing their NDA. The time spent waiting for the end of the patent period and then repeating the approval process for a drug that had already proven safe and effective resulted in an extension of the drug’s patent period. Generic competitors were prevented from entering the field immediately upon expiration of the patent because they had not, and by virtue of the patent monopoly, could not, have undertaken the required testing. When this distortion was assailed as unfair, innovative drug manufacturers countered by pointing to the portion of their patent period lost to the same initial regulatory approval process.

This dispute over distortions in the patent term found expression in *Roche Products, Inc. v. Bolar Pharm. Co.*<sup>26</sup> In *Roche*, the Federal Circuit was faced with a generic drug manufacturer that produced samples of a patented drug in order to conduct safety and efficacy tests in anticipation

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23. *Id.* (stating that “use is disqualified from the defense if it has the ‘slightest commercial implication[. . . [is] in keeping with the legitimate business of the alleged infringer[.] . . . [or] is in any way commercial in nature.”). The author struggles to conceive of any activities undertaken by any entity that would not satisfy these elements.

24. 21 U.S.C. § 355(b) (2005).

25. Rick Mullin, *Drug Development Costs About \$1.7 Billion*, CHEMICAL & ENGINEERING NEWS (Dec. 15, 2003), available at <http://pubs.acs.org/cen/topstory/8150/8150notw5.html>.

26. *Roche Products, Inc. v. Bolar Pharm. Co. Inc.*, 733 F.2d 858 (Fed. Cir. 1984), cert. denied, 469 U.S. 856 (1984).

of the patent's expiration. In defense, the generic drug manufacturer, Bolar, claimed, *inter alia*, the experimental use exemption.<sup>27</sup> However, the court held the experimental use defense inapplicable and ruled that any use of a patented drug compound by a generic drug manufacturer before the patent's expiration constituted infringement.<sup>28</sup>

In response to *Roche*, Congress passed the Hatch-Waxman Act of 1984.<sup>29</sup> This act addressed the simultaneous compression and expansion of patent terms mentioned above that occurred under the existing FDA regime: the running of the patent period during the innovator's extended clinical trials and the *de facto* extension of the patent period resulting from requiring generic manufacturers to redundantly perform these same trials. To remedy these inequities, Congress established a new type of FDA filing called an abbreviated new drug application (ANDA).<sup>30</sup> Instead of reinventing the pharmaceutical wheel by performing anew the same trials done by the innovator, under the ANDA, generic drug manufacturers must simply prove that their version of a previously approved drug is bioequivalent.<sup>31</sup> Since bioequivalence simply means that the generic drug works in the same way and has the same effect on humans as the innovator, the result is a significantly less expensive and a quicker approval process.<sup>32</sup> The Act further provided for the extension of a drug's patent term depending on the length of time required for regulatory approval of its NDA.<sup>33</sup> In addition to simplifying the approval process, the Act permitted certain experimental use of patented products prior to patent expiration. It provided for pre-expiration use by incorporating a new affirmative defense to infringement.<sup>34</sup> The relevant part of the Act reads:

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 . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the

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27. *Roche*, 733 F.2d at 862. It is interesting to note that the severely restrictive view of the experimental use exemption that bolstered the CAFC's decisions in *Embrex* and *Madey* has much of its roots in *Roche*. Most troubling is the fact that *Roche* did not need to so restrict the experimental use exemption. Bolar was clearly and admittedly using Roche's patented compound for a commercial purpose. The *Madey* court, however, cited *Roche* for the proposition that the non-profit, non-commercial nature of the defendant is irrelevant.

28. *Id.* at 863.

29. 28 U.S.C. § 2201 (1993); 35 U.S.C. §§ 156, 271, 282 (2003).

30. 21 U.S.C. § 355(j) (2005).

31. 21 U.S.C. § 355(j)(7)(B) (2005).

32. 21 CFR § 320 (2005) (describing requirements for bioequivalence).

33. 35 U.S.C. § 155 (2005).

34. Freiburg, *supra* note 12, at n.92.

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manufacture, use, or sale of drugs or veterinary biological products.<sup>35</sup>

This new defense, providing that patented drugs may be lawfully used if the use is reasonably related to the submission of information to the FDA, has been deemed the Hatch-Waxman or § 271(e)(1) safe-harbor.<sup>36</sup>

### III. *INTEGRA V. MERCK* AT THE FEDERAL CIRCUIT

#### A. *The Safe-Harbor is Quickly Expanded*

The impetus behind § 271(e)(1)'s safe-harbor was the frustration of generic drug manufacturers and consumers with the lengthy and duplicative process of generic drug approval. The United States Supreme Court, however, quickly expanded the safe-harbor's reach to innovative medical devices.<sup>37</sup> In *Eli Lilly and Co. v. Medtronic, Inc.* the applicable law was the Federal Drug and Cosmetics Act (the FDCA), a "[f]ederal law which regulates . . . drugs"<sup>38</sup> and requires submission of information for the approval of medical devices. Demonstrating his penchant for close statutory reading, Justice Scalia held that the structure of the Hatch-Waxman Act as a whole indicated that it must have been intended to include medical device use in the § 271(e)(1) safe-harbor.<sup>39</sup> Thus, the Court held that the language of § 271(e)(1) covered non-patent holders' use of patented inventions as long as the use is related to submission of information required under Federal law.<sup>40</sup>

#### B. *Integra v. Merck Halts the Expansion*

Despite its liberal reading of the § 271(e)(1) safe-harbor in *Eli Lilly*,<sup>41</sup> the Federal Circuit reversed course and limited the provision's applicability in *Integra*.<sup>42</sup>

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35. 35 U.S.C. § 271(e)(1) (2005).

36. This Comment will refer to it as the "§ 271(e)(1) safe-harbor."

37. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), *vacated*, 915 F.2d 670 (Fed. Cir. 1990).

38. *Eli Lilly*. 496 U.S. at 661.

39. *Id.* at 669-70.

40. *Id.* at 672-73.

41. *Id.* at 664.

42. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *corrected by* 2003 U.S. App. LEXIS 27796 (July 10, 2003).

*1. Facts*

*Integra v. Merck* involved a compound consisting of a three amino acids segment of a protein patented by Integra Lifesciences. Called the RGD peptide, this compound was known to be involved in process called cell adhesion, which had possible applications in wound healing and prosthetics. In addition, David Cheresch, a researcher at The Scripps Research Institute,<sup>43</sup> discovered that the RGD peptide had the ability to inhibit angiogenesis, the process by which new blood vessels are formed in the body.<sup>44</sup>

Sensing the importance of Cheresch's discovery, Merck, a pharmaceutical company,<sup>45</sup> entered into an agreement with Cheresch and Scripps under which Merck would provide funding and RGD peptides to Cheresch's lab.<sup>46</sup> Under the agreement, Cheresch was to perform his research with the purpose of developing potential drug candidates that Merck would then shuttle through the regulatory approval process.<sup>47</sup> Cheresch soon determined that three cyclic versions of the peptide were most effective at inhibiting angiogenesis.<sup>48</sup> These peptides were then further studied by Cheresch's lab "to evaluate [their] specificity, efficacy, and toxicity . . . for various diseases, to explain the mechanism by which these drug candidates work, and to determine which candidates were effective and safe enough to warrant testing in humans."<sup>49</sup>

Upon learning of the Scripps-Merck agreement, Integra<sup>50</sup> offered to

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43. "The Scripps Research Institute, one of the country's largest, private, non-profit research organizations, has always stood at the forefront of basic biomedical science, a vital segment of medical research that seeks to comprehend the most fundamental processes of life. In just three decades the Institute has established a lengthy track record of major contributions to the betterment of health and the human condition." Taken from Scripps' website, *available at* <http://www.scripps.edu/intro/overview.html>.

44. *Integra*, 331 F.3d at 863 (noting that anti-angiogenesis has potential for application in treating cancer, rheumatoid arthritis and other debilitating diseases).

45. "Merck is a global pharmaceutical and chemical company with sales of EUR 5.9 billion in 2004, a history that began in 1668, and a future shaped by 28,900 employees in 54 countries . . . Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds a 73% interest and free shareholders own the remaining 27%. The former U.S. subsidiary, Merck & Co., has been completely independent of the Merck Group since 1917." Taken from Merck KGaA's website, *available at* <http://www.merck.de/servlet/PB/menu/1007020/index.html>.

46. *Integra*, 331 F.3d at 863.

47. *Id.*

48. *Id.*

49. *Id.* These tests included assays to determine the action of the cyclic RGD peptides, including, *inter alia*, toxicology, half-life in the bloodstream, and the optimum mode of administration. *Id.*

50. "Integra LifeSciences Holdings Corporation is a diversified medical technology company that develops, manufactures, and markets medical devices for use in a variety of applications. The primary applications for our products are neuro-trauma and neurosurgery, reconstructive surgery, general surgery, and soft tissue repair. However, our surgical instrument product lines are used in



license use of the peptides to Cheresch. However, negotiations failed and Integra filed a patent infringement suit against Scripps, Dr. Cheresch, and Merck. The United States District Court for the Southern District of California dismissed the suit against Scripps and Cheresch but ruled that Merck had infringed Integra's patents in part because § 271(e)(1) did not immunize Merck from liability.<sup>51</sup>

## 2. Federal Circuit majority decision

In his opinion for the court, Judge Rader found support for his restrictive reading of the § 271(e)(1) safe-harbor by focusing on the Hatch-Waxman Act's legislative history.<sup>52</sup>

According to the court, by limiting the safe-harbor to "solely . . . uses reasonably related to the development and submission of information," Congress intended that the exemption be narrowly construed.<sup>53</sup> Specifically, the "reasonably related" test focuses the analysis on the information that is to be submitted to the FDA.<sup>54</sup> Although some experiments that do not directly produce information to the FDA might be allowed, the term "solely" requires that these activities be closely scrutinized by the court.<sup>55</sup> Thus, the court held that Merck's activities did not meet the "reasonably related" test.<sup>56</sup> Merck's experiments constituted general biomedical research and were aimed at identifying new pharmaceutical compounds.<sup>57</sup> Since "the FDA has no interest in the hunt for drugs," the experiments were not reasonably related to the submission of information to the FDA and thus were not exempted from infringement liability.<sup>58</sup>

As mentioned above, Judge Rader's decision was influenced by the

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virtually all surgical disciplines. . ." Taken from Integra's website, *available at* [http://www.integrals.com/corporate\\_info/profile.asp](http://www.integrals.com/corporate_info/profile.asp).

51. Integra had changed the nature of its action against Cheresch and Scripps from one seeking damages for infringement to one for declaratory judgment, which would be somewhat akin to an order simply enjoining them from further infringement. This declaratory judgment action was dismissed on motion by Cheresch and Scripps. *Integra*, 331 F.3d at 863. Note that the District Court found that Scripps' pre-1995 activities were exempt from infringement liability under the common-law research exemption. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2379 (2005). Because, however, the issue was not appealed to the CAFC or the United States Supreme Court, no decision on the applicability of the exemption was made by these higher courts. *Integra*, 331 F.3d at 863, n.2; *see* discussion, *infra* Part V.

52. *Integra*, 331 F.3d at 866-67.

53. *Id.* at 866.

54. *Id.*

55. *Id.* at 865-66.

56. *Id.* at 866-67.

57. *Id.*

58. *Id.* at 866.

Hatch-Waxman Act's legislative history.<sup>59</sup> For instance, Judge Rader noted that § 271(e)(1) was passed essentially in response to *Roche*.<sup>60</sup> He found especially important legislative comments indicating that the exemption was initially drafted to apply to "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute."<sup>61</sup> Although, the court was precluded by *Eli Lilly* from holding that § 271(e)(1) applied exclusively to generic drug testing, based on the legislative history, it adopted a narrow reading of the exemption.<sup>62</sup>

The court's opinion ranged from the somewhat contradictory to the genuinely thought-provoking. For instance, Judge Rader applied a restricted § 271(e)(1) in determining that Merck's activities were "far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market."<sup>63</sup> The court justified its holding by appealing to the rubric of generic drugs while claiming that § 271(e)(1)'s reach was not so limited. It then stated the obvious, that § 271(e)(1) did not apply to all experimental activity that at some point, "however attenuated," may lead to an FDA submission as a straw-man argument it quickly blew down.<sup>64</sup> On the other hand, the court was well founded in its concern over the possible future of biotech research tool patents under any other interpretation of § 271(e)(1). Specifically, Judge Rader worried that extending the safe-harbor to the Scripps-Merck activities would "effectively vitiate the exclusive rights of patentees owning biotechnology tool patents."<sup>65</sup>

### 3. Judge Newman's dissent

Judge Newman penned a vigorous dissent in *Integra v. Merck* in which she challenged the majority's inattention to the common-law experimental use exception and its limiting treatment of the § 271(e)(1)

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59. See *supra* Part II.

60. *Integra*, 331 F.3d at 865; see also *supra*, n.29 and accompanying text.

61. *Id.* (quoting H.R. REP. NO. 98-857, at 8 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, at 2692).

62. *Id.* at 867 (citing *Eli Lilly*, 496 U.S. 661). It is interesting that the court's original opinion in *Integra* was amended. The errata decision, reported at 2003 U.S. App. LEXIS 27796, softened the restrictive wording of the opinion near the beginning of page \*17, so as to bring it in line with *Eli Lilly* (i.e. the original *Integra* opinion was much more explicit in its limitation of the § 271(e)(1) safe-harbor to generic drugs).

63. *Id.* "[D]rug already on the market" being an obvious reference to the testing involved in the development of generic drugs.

64. *Id.*

65. *Id.*

safe-harbor.<sup>66</sup>

Newman essentially argued that the experimental use exception should extend to any testing performed on the patented invention itself, regardless of the possible downstream commercial applications. While not even mentioned by the majority, she distinguished between *using* a patented invention to perform tests or experiments and *testing or experimenting on* the patented invention itself.<sup>67</sup> She identified acceptable purposes for experimenting *on* a patented invention as including “understand[ing] it, or to improve upon it, or to find a new use for it, or to modify or ‘design around’ it.”<sup>68</sup> Furthermore, she emphasized that experimentation with an obvious commercial intent should not remove the activities from the common-law research exemption so long as the tests were aimed at understanding, improving, or modifying the patented invention.<sup>69</sup> This distinction is important because it ameliorates the majority’s concern that an expansive safe-harbor would vitiate the value of research tool patents.<sup>70</sup> Therefore, under Judge Newman’s analysis, since Cheresch’s experiments focused on studying the properties of the cyclic RGD peptides themselves rather than using the peptides to test other compounds,<sup>71</sup> they qualified for the infringement exception.<sup>72</sup>

Judge Newman also identifies logical fallacies in the majority decision and answers the majority’s public policy concerns. First, Newman exposes a logical inconsistency created by the majority opinion: extremely early stage research conducted by a qualified institution would be exempt from liability under the experimental use exception, late stage research that creates information that is submitted to the FDA is exempted under § 271(e)(1), and the intervening research period is a “strange . . . kind of limbo” in which infringing activities are not shielded from liability.<sup>73</sup> Second, she argues that recognition of an

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66. Note that the author has adopted Judge Newman’s convention of equating the common-law research exemption and the experimental use exception. These two terms are synonymous because Judge Newman sees the exemption as reaching use (generally in the form of experimental research) that is aimed at understanding, modifying, or improving a patented invention itself. *See supra* note 49.

67. *Integra*, 331 F.3d at 877-78 (Newman, J., dissenting). This distinction is cited by Newman to respond to the majority’s worries about the “vitiat[ion]” of all biotech research tools.

68. *Id.* at 875 (Newman, J., dissenting).

69. *Id.* at 876 (Newman, J., dissenting).

70. Though Newman was specifically discussing the research exemption and not the § 271(e)(1) safe-harbor, Newman sees the two constructs as intertwined and complementary.

71. Note that several of the Scripps-Merck experiments did appear to in fact use the RGD peptides as positive controls in testing the anti-angiogenesis properties of other drug candidates. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2378-79 (2005). The implications of this bewilderingly unnoticed fact will be discussed in PART V.

72. *Integra*, 331 F.3d at 876 (Newman, J., dissenting).

73. *Id.* at 877.

experimental use exemption ought not and need not be a free-for-all that eviscerates the rights of patent-holders because testing *using the invention* rather than testing *on the invention* would still be an infringement; attention must be paid “[to] the mechanisms of the creation, development, and use of technical knowledge, and [to] today’s complexity of interactions among invention and the innovating fruits of invention.”<sup>74</sup>

With regards to the specific facts of *Integra*, Newman argues that incorporation of the experimental use exception in conjunction with § 271(e)(1) avoids the majority’s conundrum by providing more continuous exemption coverage.<sup>75</sup> As noted above, the majority’s strict understandings of both the experimental use exemption and the § 271(e)(1) safe-harbor create a limbo-like no-man’s land in which Merck inexcusably infringed *Integra*’s patents.<sup>76</sup> While § 271(e)(1) admittedly should not “reach back down the chain of experimentation to embrace [the] development and identification of new drugs,” the experimental use exemption should be co-extensive with § 271(e)(1) such that the latter essentially picks up where the former left off.<sup>77</sup>

#### IV. MERCK V. INTEGRA AT THE UNITED STATES SUPREME COURT

##### A. Opinion and Analysis

Much ink was spilled in the pages of law reviews in response to the Federal Circuit’s *Integra* decision.<sup>78</sup> On appeal to the United States Supreme Court, *Merck* elicited *amicus* briefs from far-ranging friends of the court, including major players in the biotech, pharmaceutical, and research tool industries.<sup>79</sup> The stakes for the entire biotech and drug development industries could not have been higher.

With his signature emphasis on statutory language, Justice Antonin Scalia delivered the unanimous opinion for the Court.<sup>80</sup> Scalia stated that

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74. *Id.* at 876. See also Dreyfuss, *supra* note 1 (discussion of unique issues in biomedical research that support a more vigorous experimental use exemption).

75. Further supporting exemption from liability is the fact that *Integra*’s predecessor, *Telios*, had been unsuccessful in finding a useful application for the RGD peptides. *Integra*, 331 F.3d at 876 (Newman, J., dissenting). Some recent proposals for patent reform have centered on forcing patent holders to develop the technology in their patents.

76. *Id.* at 876.

77. *Id.* at 877.

78. See, e.g., Freeburg, *supra* note 12; Dreyfuss, *supra* note 1.

79. Including Genentech, Biogen IDEC, Eli Lilly, Wyeth, Pfizer in support of Merck and Affymetrix, Vaccinex, and several research universities in support of *Integra*.

80. This author trusts that the reader is aware of the rarity of a unanimous decision from today’s Court, let alone one written by arguably the Court’s most polarizing member. Furthermore,

the text of the statute indicated that it extended to “all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”<sup>81</sup> Most significant in Scalia’s paraphrase is his use of “all” and “any”;<sup>82</sup> apparently the Court intended to interpret the statute very broadly. Thus, unlike in the District Court and the Federal Circuit, the phase of research from which the information is garnered is not important to the Court. In fact, the Court stated that even preclinical studies are within the scope of the safe-harbor.<sup>83</sup>

Under Scalia’s formulation of the rule, the key inquiry is identifying what information the FDA might be interested in receiving in regards to a drug candidate.<sup>84</sup> Previously, lower courts struggled with defining which information the FDA would be interested in, with one court even taking the unique course of deferring to the FDA in deciding if a particular defendant’s activities were “reasonably related.”<sup>85</sup> Respondent *Integra* attempted a definition that experimentation into a drug candidate’s “efficacy, mechanism of action, pharmacokinetics and pharmacology are not reasonably included in an [investigational new drug application] (IND) or an NDA, and are therefore outside the scope of the exemption.”<sup>86</sup> In addressing this definition, the Supreme Court quickly and simply dispatched it by pointing out that the FDA requires that IND’s contain summaries of at least some of those factors which were deemed unimportant by *Integra*.<sup>87</sup> As the FDA is charged with deciding whether clinical trials of an investigational drug would pose an unreasonable risk, a drug developer would be shielded from infringement liability for acts giving rise to any information relied upon by the FDA in making this risk determination.<sup>88</sup>

Scalia then proceeded to evaluate the two-part rationale the Federal Circuit used to support its definition of the safe-harbor rule. In the first part of its rationale, the lower court noted that the FDA does not have

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the brevity of the decision belies its significance.

81. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380 (2005).

82. *Merck*, 125 S. Ct. at 2383 (2005) (§ 271(e)(1) exempts “from infringement *all* uses of patented compounds ‘reasonably related’ to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs”) (emphasis in original).

83. *Id.* at 2380 (2005).

84. *Id.* at 2382.

85. *Nexell Therapeutics Inc. v. Amcell Corp.*, 143 F. Supp. 2d 407 (D. Del. 2001). The FDA declined to decide the case, and the judge held that activities related to clinical trials were not infringing.

86. *Merck*, 125 S. Ct. at 2381.

87. *Id.* (citing FDA regulations at 21 CFR §§ 312.22(a), (a)(5) (2005)).

88. *Id.* at 2381 (citing 21 U.S.C. § 355(i)(3)(B)(i); 21 CFR § 312.23(a)(8) (2005) (requiring applicants to include pharmacological and toxicological studies that serve as the basis of their conclusion that clinical testing would be “reasonably safe”)).

any interest in the hunt for drugs; especially damning was the fact that the experiments performed by Cheresch did not yield any information which was actually submitted to the FDA.<sup>89</sup> Scalia perceived this to be a *de facto* restriction of the application of the safe-harbor rule to only generic drugs.<sup>90</sup> Furthermore, he reasoned that the Federal Circuit's rationale ignores the realities of drug development, where even late stage drug trials are often abandoned and result in no submission to the FDA.<sup>91</sup>

In contrast, by adding the words "all" and "any" to the statute, Congress permitted the safe-harbor rule to do what it was designed to do – protect a drug maker that ". . . has a reasonable basis for believing that a particular patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA."<sup>92</sup> However, this more expansive reading of the rule is not all-encompassing. Instead, this language limits the extent of the safe-harbor, suggesting that some knowledge of the drug's mechanism of action and physiological effect is required before the infringing activities may be exempted.

The Court addressed the Federal Circuit's second rationale by essentially agreeing that the safe-harbor does not embrace all activities that may at some "attenuated" point lead to an FDA submission.<sup>93</sup> The Court declared that research conducted with the reasonable belief that the drug will have a desired effect is reasonably related to the submission of information to the FDA.<sup>94</sup>

### B. Balancing Protection with Purpose

The importance of the freedom granted to research institutions and drug companies by the Court's holding cannot be overstated. The Federal Circuit had in essence restricted the extent of the safe-harbor to generic drug development.<sup>95</sup> Although under *Eli Lilly*, the decision could not explicitly provide such a restriction, it did in effect do so by indicating that only those activities that were certain to produce information

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89. *Id.* at 2382 (quoting *Integra*, 331 F.3d at 865).

90. *Id.* at 2383. Only in the realm of generic drugs could an experimenter have sufficiently sure knowledge that a particular experiment would actually result in submission of information to the FDA. *Id.*; see *supra* notes 62 and 63.

91. *Id.* at 2383 (noting that the Federal Circuit's construction of § 271(e)(1) renders the exemption "illusory").

92. *Id.* at 2382.

93. *Id.*

94. *Id.*

95. *Id.* at 2383.

submitted to the FDA would be exempted from liability.<sup>96</sup> The Court correctly recognized that this take on the statute does not resonate with the hit-and-miss nature of drug development.<sup>97</sup>

The importance of the Court's decision is not likely to be lost on commentators, if their uproarious reaction to *Integra* is any indication.<sup>98</sup> Rochelle Dreyfus points out that *Madey* effectively destroyed the common law research exemption and that *Integra* limited the § 271(e)(1) to generic drug development.<sup>99</sup> In contrast, after *Merck*, drug developers are now much more free to test patented compounds and their derivatives for potential pharmaceutical benefits. As an example, consider the fact that drug companies have libraries compiled of thousands of chemical compounds, many of which are "scaffold" compounds to which different side chains and active groups may be added to achieve a certain physiological effect.<sup>100</sup> Under *Integra*, unauthorized use of such a compound in experiments to test the compound's safety and efficacy would constitute an infringement unless the experiments involved

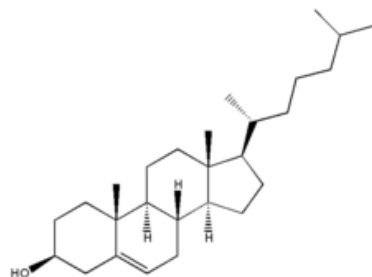
96. *Id.*

97. *Merck*, 125 S.Ct. at 2382-83 (noting that even late-stage clinical testing is not eventually submitted to FDA since late-stage drug candidates can prove unworthy of submission for FDA approval).

98. *Dreyfuss*, *supra* note 1; *Freeburg*, *supra* note 12. See generally Note, *Integra v. Merck: Limiting the Scope of the 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193 (2004); Angela M. Davison, *Shrinking Waters in the Safe Harbor: Has Integra Lifesciences v. Merck Turned the Tide by Narrowing Available Exempted Infringing Uses?*, 59 FOOD DRUG L.J. 79 (2004).

99. *Dreyfuss*, *supra* note 1, at 461.

100. For instance, "steroid" refers to a broad class of chemical compounds often involved in intercellular signaling. A steroid consists of a core component, or moiety, made up of several carbon rings (the hexagons and pentagon in the diagram below). A long carbon "tail" (the zig-zag extending up and to the left) has been added to the steroid "scaffold" to form cholesterol. This example begins to give the reader an idea of the nearly infinite range of compounds that pharmaceutical companies must screen in order to find a suitable drug candidate. The reader will also begin to see the stranglehold a company would have if it owned a patent on the steroid core and other companies could not even use the steroid to develop additions and modifications.



humans.<sup>101</sup> The Supreme Court, recognizing the vital role drug companies play in the health of society, ruled that uses similar to the imaginary modified scaffold above are shielded from liability so long as the experimenter reasonably believes that the experiments will lead to information that could ultimately be submitted to the FDA.<sup>102</sup>

Perhaps most importantly, the Court appears to have reaffirmed the fundamental purpose behind the patent system: scientific and technological advancement with the understanding that such will improve people's lives.<sup>103</sup> Thus, although intellectual property protection is the stated goal of patent protection, the underlying policy of patent protection is improvement of the human condition. Accordingly, the Hatch-Waxman Act modified patent protection in order to provide a means for faster development and delivery to the public of affordable generic drugs by carving out a limitation of the patent holder's rights (which had been artificially created by the patent law in the first place).<sup>104</sup> Likewise, while the first patent office administrator, Thomas Jefferson, and others have recognized the importance of patent protection to the advancement of science, this recognition has always been tempered by a visceral suspicion of monopolies.<sup>105</sup> When a patent has an overwhelming effect of stifling innovation, it has outgrown the justification for its existence and should be reined in. The Court in *Merck* saw § 271(e)(1) as guarding against this: giving drug companies more room in which to work and advance knowledge in medicine, the most vital of areas.

#### V. MERCK'S MISSED OPPORTUNITIES

While *Merck* did much to correct a worrisome trend in the Federal Circuit, neither the common law research exemption nor the applicability of § 271(e)(1) to research tools were dealt with adequately, either because the parties did not litigate these issues or because the Court's

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101. Generally speaking, mere addition of elements to a patented invention does not evade infringement. *Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001).

102. Recall that there appears to be the added requirement that the researcher have some idea of the physiological effect of the drug. *See Merck*, 125 S. Ct. at 2383.

103. The "embarrassment" of a patent monopoly is tolerated only to the extent it spurs innovation. *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) (quoting Thomas Jefferson, first administrator of the patent system in the United States). *See infra* Part V for more discussion of this compromise and why the courts must always be mindful of the basis of patent law.

104. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003); *corrected by* 2003 U.S. App. LEXIS 27796, \*11 (July 10, 2003) (quoting *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997)).

105. *Graham*, 383 U.S. at 7-9.



unusually taciturn opinion simply did not address them.

*A. Common Law Research Exemption*

As Judge Newman pointed out in her dissent, *Integra v. Merck* offered an excellent opportunity to reinvigorate the common law research exemption.<sup>106</sup> Unfortunately, the Court missed this opportunity. For example, the Merck-Scripps collaboration aimed initially at synthesizing and studying the RGD peptide and derivatives in the hopes of understanding the full extent of their biological properties. Under the Court's decision, unless the researchers had "a reasonable belief that the compound [would] cause the sort of physiological effect [they intended] to induce," any tests conducted would not have been covered by the safe-harbor rule.<sup>107</sup> In contrast, under Judge Newman's formulation of the experimental use exemption, such activities would have been shielded from liability regardless of any FDA submission.<sup>108</sup>

The most important consequence of a resurrected experimental use would be the added freedom inventors would have to advance technology beyond its current state, as represented by the patented invention. An inventor's ability to "design around" and/or improve upon the patented invention is seriously limited if his access to the invention is restricted to his ability to obtain a license.

In addition, a meaningful common law exemption accommodates intellectual property protection, while at the same time balancing it with the unique aspects of biotechnology.<sup>109</sup> Indeed, the experimental use exemption was acceptable in its exceedingly narrow form because, before biotech, there existed a clear conceptual and legal division between fundamental science and its application in end-products. Fundamental discoveries—such as the scaffold compounds mentioned in the above example—were not patentable and only the downstream applications of these discoveries would be granted a patent that was limited in scope to reach only other end-products.<sup>110</sup> In biotechnology, by contrast, frontier discoveries often have immediate applications and are granted broad upstream patents that severely hamper the activities of subsequent researchers.<sup>111</sup> This has been described as the problem of the

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106. *Integra*, 331 F.3d at 874 (Newman, J., dissenting).

107. *Merck*, 125 S.Ct. at 2383.

108. *Integra*, 331 F.3d at 876 (Newman, J., dissenting).

109. Dreyfuss, *supra* note 1, at 463 (noting that the "fruits of biotechnology," unlike in many other areas of science and technology, often have immediate commercial applications).

110. See, *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966); see also, *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005).

111. *Fisher*, 421 F.3d at 1372.

anticommons and recognition of its severity has been increasing.<sup>112</sup> If access to fundamental scientific discoveries—such as antibodies against a certain cell-receptor or the purified form of a gene known to exist in people particularly susceptible to breast cancer<sup>113</sup>—is limited by broad patents and the abolition of the experimental use exception, innovation will be asphyxiated.

Admittedly, the Federal Circuit's and the Supreme Court's refusal to address this issue is technically well-founded as the parties did not raise it on appeal.<sup>114</sup> The Supreme Court, at least, has shown itself amenable to deciding issues not raised at trial or on appeal but whose policy implications beg for resolution.<sup>115</sup> Further, Judge Newman's impassioned plea for the resurrection of the experimental use exception and both courts' proclivity for deciding or at least discussing collateral issues give one pause when considering what might have been had the Court taken the liberty to address this issue.

### B. Research Tools

Perhaps the most important issue in *Merck* was the application of § 271(e)(1) and to a lesser extent the common-law research exemption to patented research tools. Yet, discussion of protection of research tools was largely ignored because the Court erroneously deemed it not to be found in the record.<sup>116</sup>

#### 1. Misreading the record

In one seemingly innocuous sentence in his recitation of *Merck's*

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112. Freeburg, *supra* note 12, at 399 (discussing Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, *Science* 698 (1998)). The problem of the commons was described as the inefficient use of a resource due to its being owned by all of society "in common." The problem of the anticommons, in contrast, exists when too many parties hold exclusive rights and the elbow room required to advance science is lacking.

113. Dreyfuss, *supra* note 1, at 459-60 (discussing example of patenting of the BrcA1 gene).

114. *Integra*, 331 F.3d at 863, note 2.

115. For a recent, controversial example of the Supreme Court looking into a question not raised or preserved at trial, briefed on appeal to the Federal Circuit, or mentioned in the request for certiorari, see *LabCorp v. Metabolite*, U.S. Supreme Court Docket No. 04-607, available at <http://www.supremecourtus.gov/docket/04-607.htm> (asking the Solicitor General to brief the Court on the patentability of the claims at issue in view of *Diamond v. Diehr's* ruling that "one cannot patent 'laws of nature, natural phenomena, and abstract ideas.'"). This question was not broached by either party at trial nor in the lower courts, but the Court in its discretion has at least expressed interest in deciding it. See Amicus Curiae Brief of American Intellectual Property Law Association in Support of Respondent at 3-4, n.5, *Laboratory Corporation of America Holdings, v. Metabolite Laboratories, Inc.*, 370 F.3d 1354 (Fed. Cir. 2004) (No. 04-607).

116. *Infra*, note 119.

facts, Justice Scalia stated that “Scripps used the RGD peptide in . . . tests as ‘positive controls’ against which to measure the efficacy of the mimetics.”<sup>117</sup> To the casual reader this may seem unimportant, but it represents one of the key facts of the case. Scripps not only studied the RGD peptides themselves for their efficacy, safety and mode of action, but used them as a tool against which to compare the efficacy of other compounds. This use, since it is not experimentation on the patented invention itself but use of the invention in conducting research on another compound, is exactly the type of use that should not fall behind the shield of Judge Newman’s reinvigorated experimental use exception.<sup>118</sup> Likewise, those in the pharmaceutical and biotech industries recognize this sort of use as that of a research tool.<sup>119</sup>

*Merck* could be read to exempt, under § 271(e)(1), the use of a patented compound as a research tool to study another compound that is a drug candidate, but this reading would probably be an impermissible stretch.<sup>120</sup> Trying to assuage the Federal Circuit’s fears that patents on research tools would be effectively eviscerated if activities such as *Merck*’s were exempted from infringement liability, the Court expressly stated that its holding did not apply to research tools.<sup>121</sup> It is not clear whether the Court refused to decide the question because it was not argued—which would be an acceptable reason for omitting such a vital issue—or because the record did not include use of research tools—which would be erroneous. The applicability of § 271(e)(1) to research tools was left open by the Court to be decided another day. But, as will be shown below, this was arguably the most important aspect of the case!<sup>122</sup>

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117. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2379 (2005) (emphasis added).

118. *Integra*, 331 F.3d at 877-78 (Newman, J., dissenting). Note that Judge Newman, unlike the *Integra* majority, joined and the Supreme Court in misreading the record as containing no use of the peptides as research tools. *Id.*

119. Brief for Invitrogen Corp. et al. as Amici Curiae in Support of Respondent at 18-20, *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (No. 03-1237); see also *Integra*, 331 F.3d at 872, n.4.

120. The author admits, however, that there is language in *Merck* that could allow such a reading. See *Merck*, 125 S. Ct. at 2382.

121. *Merck*, 125 S. Ct. at note 7 (stating that it was “apparent from the record” that the RGD peptides were not used as research tools).

122. As Judge Newman pointed out in her dissent, the Federal Circuit essentially acknowledged that Scripps used the peptides as a research tool and proceeded to decide that this use did not fall within the § 271(e)(1) safe-harbor. *Integra*, 331 F.3d at 877-78 (Newman, J., dissenting). The Supreme Court should have treated research tools in its decision, even though this point was not appealed, because a reversal of the Federal Circuit’s decision could be interpreted to mean that § 271(e)(1) does apply to research tools regardless of the Court’s attempts to limit its holding. Brief for Invitrogen Corp. et al. as Amici Curiae in Support of Respondent at 19-20, *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (No. 03-1237).

2. *Why unique biotech issues require both the common law exemption and a vigorous § 271(e)(1) safe-harbor*

Biotechnology and biomedical research depend largely upon the use of patented compositions of matter for their advancement. Antibodies, purified DNA sequences, cell surface receptors and other biological products are essential components to any research project. However, broad patents have been granted on such “tools,” making even fundamental biomedical research an expensive or, in cases where the patent holder belligerently refuses to license, an impossible endeavor. As Rochelle Dreyfuss has noted, biotech has changed the former paradigm that consisted of linear advancement from unpatentable fundamental research and discovery to patentable consumer end-products.<sup>123</sup>

It is a core tenet of patent law that products, laws, and phenomena of nature are not patentable.<sup>124</sup> An obvious reason for this is that the inventor has arguably not invented anything when he discovers a law or product of nature and thus deserves no patent rights.<sup>125</sup> Perhaps the firmest basis for this universal bar on the patentability of products of nature, though, is that these things form the foundation for further research,<sup>126</sup> and allowing their patenting would stifle development of applications that might stem from them. In the arena of biomedical research and biotechnology, however, elements that skirt the line between products of nature and products of man, such as an isolated human gene or an antibody to a particular antigen, *are* patentable. In the exemplary case of a patented gene, patentability may be defensible based on the presence of direct, immediate commercial applications, such as using the gene as a tool to diagnose certain diseases or predispositions. In other words, in biotech the line between a fundamental law or product of nature and an application of the law or end-product is blurred.

This quandary may be resolved by holding fast to the basic principles of the American patent system. Monopolistic patent rights are not awarded based on some Lockean system of reward or desserts.<sup>127</sup> Patent rights are artificial creations of the patent law *granted by legislative*

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123. Dreyfuss, *supra* note 1, at 463.

124. *Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980).

125. Under this Lockean analysis, patents are awarded based on the rights or desserts of the inventor – i.e. the inventor has mixed his labor with the raw materials in order to create a new invention that has, in turn, become his. It is important to note, however, that even this philosophical view of patents is not the one embraced by the United States. Robert P. Merges, et al., *Intellectual Property in the New Technological Age* 119 (3rd ed., Aspen Publishers 2003).

126. *Diamond v. Diehr*, 450 U.S. 175 (1980); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

127. See *supra* note 103.

*grace* “to promote the Progress of Science and useful Arts.”<sup>128</sup> The ultimate value<sup>129</sup> in the isolation of a gene associated with a particular disorder is its potential for leading to a cure, not simply identifying the people who have the disorder. This is where science and the useful arts are truly advanced. Researchers, especially those at universities and other non-profit research institutions (such as Scripps), should have free access to such genes in order to determine what the particular gene product is and how either blocking or enhancing its action would treat the disorder.<sup>130</sup> Further advancement is restrained, however, if the owner of the gene patent refuses to license or charges stiff fees.<sup>131</sup> In trying to secure patent holders’ rights, the founders, and Thomas Jefferson in particular,<sup>132</sup> did not intend such a disastrous suffocation of innovation.<sup>133</sup>

## VI. POSSIBLE SOLUTIONS

At its heart, this Comment is not about an obscure problem in drug patent law. While it is true that the implications of *Merck*’s omissions reach primarily into the realm of biomedical research and drug development, these fields in turn implicate health care, drug prices, and other hot button issues that are continually on the legislative agenda and seem to play a part in every presidential election.

### A. *Revitalization of Common Law Research Exemption*

Judge Newman’s dissent suggested the resurrection of the experimental use exception in order to solve the anticommons problem of squelching downstream innovation by broad upstream patents.<sup>134</sup> Certainly, this is long overdue. *Madey* arguably misconstrued the nature of university and non-profit research. Judge Newman’s formulation of the research exemption, which focuses more on the nature of the use than

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128. U.S. Const. art. I, § 8, cl. 8.

129. “Value” here refers to the societal value rather than the monetary value underlying the patent.

130. This activity would likely be included under the experimental use exception formulated by Judge Newman since the researchers are largely studying the invention itself (the touchstone of Judge Newman’s proposed experimental use analysis). *Integra*, 331 F.3d at 875-76 (Newman, J., dissenting).

131. Example of BrcA1 gene in Dreyfuss, *supra* note 1, at 459-60.

132. VI Writings of Thomas Jefferson 180-81 (H.A. Washington ed.) (as cited approvingly in *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966)).

133. See, e.g., Report of the National Institutes of Health Working Group on Research Tools App. D, available at <http://www.nih.gov/news/researchtools/appendd.htm> (June 4, 1998).

134. *Integra*, 331 F.3d at 875-76 (Newman, J., dissenting); see also Freeburg, *supra* note 12, at 399.

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the possibility of commercial applications, would do much to help return fundamental research to its previously free and open state.<sup>135</sup>

*Merck*, as noted above, will serve to lessen the impact of the death of the research exemption by expanding the applicability of § 271(e)(1). Within the limited field of research that might reasonably lead to submission of information to the FDA, *Merck* prevented the likely chilling effects that *Integra* could have had. But *Merck* failed to look at the question of whether § 271(e)(1) and the common law research exemption apply to research tools—a question with implications far beyond the preparation of drug candidates for regulatory approval.

While Judge Newman wisely suggested the revitalization of a judicial doctrine that has all but fallen by the wayside, she did not go far enough.<sup>136</sup> Judge Newman's common law exemption fails to solve the problem of a rapidly shrinking public domain in scientific research because unauthorized use of research tools is still prohibited, even if that use is by universities or other institutions to which the common law exemption should presumptively apply.

#### *B. Mandatory Waivers of Future Patent Rights by Researchers*

Rochelle Dreyfuss suggests an intriguing solution to the problem: a modified research exemption in which universities and research institutions may use a patented invention—either to study it or to use it as a research tool—without a license only if they agree in an explicitly binding waiver not to pursue patent protection for any invention that may derive from such use.<sup>137</sup>

This limited common law exemption rubric is problematic in that it takes away universities' economic incentive (a patented product) for investing large amounts of money in using the research tools to develop applications. In other words, would anyone ever sign such a waiver of patent rights?<sup>138</sup> Even still, Dreyfus' suggestion is worth deeper legislative consideration.

#### *C. Judicial Activism*

One conceivable avenue for enhancing the public domain in biotech

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135. See Dreyfuss, *supra* note 1, at 462-64 for a discussion of the previously vast public sphere in which fundamental research operated, where basic research discoveries were freely shared amongst universities. See also Introduction, *supra*.

136. *Integra*, 331 F.3d at 878 (Newman, J., dissenting).

137. Dreyfuss, *supra* note 1, at 471.

138. See *id.* at 472.

research would be to simply call on the courts to construe the utility requirement of patent law narrowly such that patenting of compositions of matter as research tools is not allowed.<sup>139</sup> There is some promise in this given a recent Federal Circuit decision in which a DNA patent was invalidated based in part on the PTO's determination that the patentee was attempting to claim "starting points for further research, not the end-point of any research effort."<sup>140</sup> Further, using a chemical compound in a research setting is arguably not a "use" within the meaning of § 271 because the invention's true utility is in its use as a drug, reagent, etc.<sup>141</sup> Another route, suggested by Judge Rader, is simply to allow the courts to apply damages in such a way as to give the common law research exemption bite.<sup>142</sup>

Courts have been exceedingly resistant, however, to read any additional limitations into the patent laws, especially regarding utility.<sup>143</sup> In response to arguments about the stifling of innovation similar to those put forth in this article, the Federal Circuit in the case of *In re Fisher* has already stated that it will not weigh such policy issues since they are "more appropriately directed to Congress."<sup>144</sup> Judge Rader's dissent in *Fisher* further indicates that research tools would probably be deemed to have a utility under § 101.<sup>145</sup> Thus any narrow construction of the "use" of patented inventions must be statutorily mandated, as discussed below.

#### D. Legislative Action

In contrast to the above suggestions, the following two-part solution requires revision of existing statutory patent law: first, a patent should be required to specifically claim the use of the invention as a research tool, much as a process patent must be clearly claimed as such; second,

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139. In order to receive a patent, an invention must new and useful. 35 U.S.C. § 101 (2005). This is commonly known as the "utility requirement" and has been a source of vexation for many seeking biotechnology patents. See, e.g., *In re Fisher*, 421 F.3d 1365, 1370 (Fed. Cir. 2005).

140. *In re Fisher*, 421 F.3d at 1370.

141. "Reagents" are chemicals that participate in reactions. Often reagents set the stage for and assist a particular reaction in taking place, but generally are not the focus.

142. *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring) (noting that the amounts involved in damage awards are naturally tailored in such a way as to make truly experimental uses essentially exempt).

143. See, e.g., *In re Fisher*, 421 F.3d at 1378; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

144. *Fisher*, 421 F.3d at 1378. Note, however, the court upheld the PTO's determination that the applicant was trying to claim "starting points for further research" when he pointed out that the DNA sequences could be used in several biomedical research applications such as gene expression microarrays.

145. *Id.* at 1379 (Rader, J., dissenting) (stating that research tools have a specific and substantial utility, namely performing scientific research).

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infringing “use” of a patented invention must be limited to using the invention in the way specifically claimed.

The first part of this rule would be accomplished by creating a research tool patent category, in addition to the present categories of compositions of matter, products by processes, and methods. Once this new category has been created, special rules governing research tool patents could be created, such as disallowing research tool claims on compositions of matter.

For instance, research tool claims could be granted by the PTO only in cases where the invention is an actual machine or implement that has utility limited only to use in a research setting—i.e. compositions of matter such as the RGD peptide at issue in *Merck* would not be patentable as research tools because they have potential usefulness as drugs. In a scenario such as the diagnostic gene “imagined” above,<sup>146</sup> the extent of patent protection would be limited to the clinical applications for which the patent was originally sought, such as diagnosis of diseases. Under this new system, the patents at issue in *Merck* would only have been allowed to exclude competitors from using the RGD peptides as compositions of matter (i.e. as a pharmaceutical drug). Use of the RGD peptides as positive controls in laboratory testing of other compounds without a license would be permitted because by statute, the RGD peptide could not be claimed as a research tool. Congress could soften any harsh effects of this new rubric by allowing the patentee to elect either claiming the invention as a research tool or a more general composition of matter, rather than requiring wholesale denial of research tool claims in the case of compositions of matter.

In combination with the above suggestion, which would restrict which uses may be included in a particular patent, limitations could also be placed on which types of use constitute infringement. For instance, when a patent specifies the utility of the claimed invention, only uses of the invention conforming to this specific utility would be considered infringing. There is precedent for limiting the infringement causes of action that may be brought under certain types of patents. For example, doctors may not, for reasons of pure public policy, be sued for infringement of a patent on a surgical procedure.<sup>147</sup>

This solution is not without its limitations. Congress does not like to

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146. Supra note 113 and accompanying text.

147. 35 U.S.C. § 287(c)(1) (2000). For discussion of proposal for a limitation on infringement liability similar to the one exempting physicians, see S. Minwalla, A Modest Proposal to Amend the Patent Code 35 U.S.C. § 287(c) to Allow Health Care Providers to Examine their Patients’ DNA, 26 Ill. U. L.J. 471-504 (2002) (proposing to expand the provision in the Patent Act that protects physicians from infringement actions for performing medical procedures to include genetic tests).



make drastic changes to the patent law, and creating an additional patent category would definitely be drastic. Furthermore, Judge Rader's concern over eviscerating research tool patents still looms and it would take deep legislative analysis to tailor the new statutory scheme so as to ensure that biotech research tool patents retain some value. But this solution promises to be surprisingly elastic and would have much room for adjustment and refinement by Congress. For instance, Congress could define this suggested new category of patents as broadly or narrowly as it deems prudent. Or it could combine solutions by only requiring research institutions such as universities to sign Professor Dreyfuss' waiver when they want exempted use of patents that fall into the suggested new category. The suggestions above are a good starting point from which Congress can plod forward.

*E. Anxiety over Changes is Not Unreasonable, Only Misguided*

Courts are reluctant to change their interpretation of the patent law and Congress is anxious about making any drastic legislative changes.<sup>148</sup> Judge Rader agonized over the effect an overly broad § 271(e)(1) safe-harbor would have on the value of research tool patents.<sup>149</sup> After all, essential to the patent system's ability to promote the progress of science and technology is its ability to incentivize research and development by providing for recuperation of costs. Others have wondered whether *any* legislation or court action can realistically put this genie back into its bottle.<sup>150</sup>

Focusing too intensely on the above concerns, however, ignores arguably more important and troubling issues in biotech patent law. For instance, the loss of the free sharing of knowledge that existed amongst universities and between universities and industry has led to a "patent thicket," navigation through which has become prohibitively expensive for many universities.<sup>151</sup> In essence, broad upstream patents in biotech

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148. See, e.g., *In re Fisher*, 421 F.3d at 1378; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); see also Michael Kanellos, Patent System's Problems Defy Easy Solutions, CNET (Aug. 4, 2005), available at [http://news.com.com/Invention+intervention—fixing+the+patent+system/2009-1001\\_3-5817175.html?tag=nl](http://news.com.com/Invention+intervention—fixing+the+patent+system/2009-1001_3-5817175.html?tag=nl) (noting the complexity of fixing patent system by legislation and the competing values and concerns that make it complex).

149. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003), *corrected by* 2003 U.S. App. LEXIS 27796 (July 10, 2003).

150. Kanellos, *supra* note 148.

151. Janice M. Mueller, The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development, 56 *Baylor L. Rev.* 917, 944-45 (2004); see also Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 *Science* 698 (1998); Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 *Wash. L. Rev.* 1, 10 (2001).

have created *Goldberg*-like entitlements in the minds of many biotech companies.<sup>152</sup> Many firms have forayed into the realm of basic research, previously reserved to universities, in the hopes of hitting the next patent mother lode. This begs the question of why the research university community must suffer because of a calculated maneuver by corporations.<sup>153</sup>

## VII. CONCLUSION

Action is needed to return the patent law to its roots. Jefferson would undoubtedly be embarrassed at how far the patent law has diverged from its original basis in promoting scientific advance.<sup>154</sup> The insinuation of Lockean principles of desserts in patent law has caused anti-competitive patents to become the norm in scientific research, rather than pro-competitive free access.

Some recent court decisions have slowed the erosion of the scientific public domain, but greater action is required. Regardless of which of the above solutions is adopted by the courts, Congress must recognize that a problem of a shrinking public sphere exists in biomedical research and that, due to judicial inertia in the case of *Merck* or counterproductive activism in the case of *Integra*, only legislative action will provide effective and lasting relief. Otherwise, scientific progress may be suffocated by the very device created to promote it.

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152. See generally *Goldberg v. Kelly*, 397 U.S. 254 (1970) (Court held that government provision of certain welfare benefits for a period of time created an entitlement to these benefits). Many companies have similarly become overly dependent on these upstream patents and thus have begun to feel entitled to them almost as of right. Notice that this attitude is fundamentally at odds with the patent law's refusal to base its grant of rights in any kind of desserts owed to the inventor. *Supra* note 103.

153. The sophistication of corporations in general and biotech firms in particular, coupled with the conscious decision to encroach on research ground previously reserved for non-profits and universities, makes the award of *Goldberg*-like entitlements especially questionable.

154. U.S. Const. art. I, § 8, cl. 8.

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