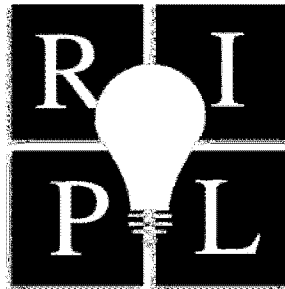


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



“AS THE FEDERAL CIRCUIT TURNS”: THE SUPREME COURT’S  
CONSIDERATION OF *MERCK V. INTEGRA* AND THE SAFE-HARBOR PROVISION

BLAIR M. JACOBS & CHRISTINA A. ONDRICK

## ABSTRACT

The Hatch-Waxman Act was enacted to balance the competing interests in the pharmaceutical marketplace between brand name and generic drug manufacturers. In the twenty years since its inception, the safe harbor provision contained in § 271(e)(1), has been interpreted to provide broad protection to those involved in research activities. However, in 2003, the Federal Circuit narrowly interpreted the safe harbor provision in a move that could potentially frustrate future research and improvements on patented technologies. *Merck v. Integra* is currently before the United States Supreme Court, who has the challenge of unraveling the competing interests involved. In order to encourage future research and clarify this area of law, the Supreme Court should adopt the approach set forth in Judge Newman’s dissenting opinion in *Integra* and exempt from infringement the use of patented products in *all* stages of research and development related to efforts to obtain FDA approval.

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“AS THE FEDERAL CIRCUIT TURNS”: THE SUPREME COURT’S  
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BLAIR M. JACOBS & CHRISTINA A. ONDRICK\*

INTRODUCTION

The high cost of health insurance and prescription drugs permeates political discourse in America. Despite the differing views regarding the best methods of solving this problem, everybody seems to agree that lower priced prescription drugs would be a good start. It is also generally agreed that the introduction of generic prescription drugs into the marketplace helps to drive down escalating prescription drug prices. The Drug Price and Competition and Patent Term Restoration Act (“Hatch-Waxman Act”), enacted more than twenty years ago, was intended to address these very concerns by dramatically changing patent food and drug laws and the manner in which the pharmaceutical industry operated.<sup>1</sup>

Part of the protection provided in the Hatch-Waxman Act is found in 35 U.S.C. § 271(e)(1), which created a safe harbor by exempting from patent infringement all conduct “reasonably related to the development and submission of information” necessary for regulatory approval from the Food and Drug Administration (“FDA”). This safe harbor provision was intended to protect generic drug manufacturers from claims of patent infringement while they were conducting research on an already-patented product in an effort to create a marketable generic equivalent once the patent on the brand name drug expired.<sup>2</sup>

For nearly twenty years following passage of the Hatch-Waxman Act, courts interpreted the safe harbor provision to provide broad protection to those involved in research activities. In 2003, however, the Federal Circuit Court of Appeals, in the case of *Integra Lifesciences I, Ltd. v. Merck KGaA*,<sup>3</sup> narrowly interpreted the safe harbor provision in a manner that could frustrate the identification and development of new drugs.

Having granted certiorari to hear the *Integra* case, the Supreme Court will now attempt to untangle competing interests, policy and societal concerns. On the one hand, the patent system is intended to contribute to progress. A narrow interpretation of the safe harbor provision does not contribute to progress because it will likely slow the willingness to conduct research on a patented product, out of fear of possible infringement allegations. According to the United States government in a brief invited by the Supreme Court, the Federal Circuit’s ruling “poses a direct and

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\* Mr. Jacobs is a partner and Ms. Ondrick is an associate in the Washington, D.C. office of the Intellectual Property group of Sutherland Asbill & Brennan LLP.

<sup>1</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360 (2000); 28 U.S.C. § 2201 (2000); 35 U.S.C. §§ 156, 271, 282 (2003)).

<sup>2</sup> See Brian Coggio & F. Dominic Cerrito, *The Safe Harbor Provision of the Hatch-Waxman Act: Present Scope, New Possibilities, and International Considerations*, 57 FOOD & DRUG L.J. 161, 162 (2002).

<sup>3</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *amended by*, No. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (Fed. Cir. July 10, 2003).

substantial threat to new drug development by dramatically narrowing the scope of protections enacted by Congress in Section 271(e).<sup>4</sup>

On the other hand, a broad interpretation of the safe harbor provision will serve as a disincentive for obtaining patent protection, as the only true value behind a patent is the right to exclude. If companies choose not to file for patents on new drugs and instead keep the new drugs protected as trade secrets, the public disclosure function of the patent system will be defeated and many new, improved ideas will never come to the attention of the public.

With these competing interests as a backdrop, the Supreme Court will soon decide this high-stakes dispute between rival pharmaceutical companies concerning the safe harbor of § 271(e)(1).<sup>5</sup> The reach of the Supreme Court’s decision will extend beyond the parties and touch not only the entire pharmaceutical industry but also the medical device industry and other industries whose products require FDA approval. This article discusses the present positions taken by the parties on appeal in briefs submitted to this point in the Supreme Court.

## I. THE HATCH-WAXMAN ACT

Congress enacted the Hatch-Waxman Act to balance competing policy interests in the pharmaceutical marketplace.<sup>6</sup> For purposes of this article and in a general sense, the pharmaceutical industry can be divided into two categories: companies developing “brand name drugs” and companies developing “generic drugs.”<sup>7</sup> Both types of drugs currently enjoy benefits under the Hatch-Waxman Act. Prior to the Hatch-Waxman Act, however, pharmaceutical companies seeking approval of brand name and generic drugs faced several obstacles. For example, brand name drug innovators seeking patent protection often lost a portion of the patent term for the drug due to the lengthy delay associated with the FDA approval process. In this circumstance, the patent issued before the drug received FDA approval, and therefore, the patent holder could not fully exploit its patent rights during the interval between the granting of the patent and the receipt of FDA approval.<sup>8</sup> That is, the patent holder could still exclude others from the market but the patent holder itself could not sell its patented drug in the marketplace.

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<sup>4</sup> Brief for the United States as Amicus Curiae Supporting Petitioner at 9, *Merck KGaA v. Integra Lifesciences I, Ltd.* (Brief In Support of Petition for Writ of Certiorari), available at No. 03-1237, 2004 WL 2851214 (filed Dec. 10, 2004).

<sup>5</sup> It is expected that Justices Sandra Day O’Connor and Stephen Breyer will not participate in the decision as they did not participate in the decision to grant the petition for certiorari. According to Justice O’Connor’s and Justice Breyer’s respective financial statements, each owns shares of Merck common stock. Tony Mauro, *Two Supreme Court Justice to Sit Out Merck Case*, New York Lawyer, at <http://www.nylawyer.com/news/05/01/011005i.html> (Jan. 10, 2005).

<sup>6</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360 (2000); 28 U.S.C. § 2201 (2000); 35 U.S.C. §§ 156, 271, 282 (2003)).

<sup>7</sup> Some companies develop brand name drugs as well as generic drugs.

<sup>8</sup> Even though a patent only grants a patent holder the right to exclude others from the market, when a patent holder sells a product in the marketplace covered by a patent, the patent holder gains market exclusivity for the product covered by the patent. The economic benefit from this exclusivity, particularly in the pharmaceutical industry, is substantial.

Similarly, significant barriers to entry into the market existed for generic drugs because a manufacturer of a generic drug could not begin the FDA approval process until after the patent on the brand name drug expired.<sup>9</sup> The end result was an effective extension of the patent term for the brand name drug. For example, in 1984, no generic drugs existed for approximately 150 brand name drugs whose patents had expired.<sup>10</sup> The Hatch-Waxman Act successfully cured one of the major barriers to entry for generics and created the modern generic pharmaceutical industry. Today most brand name drugs whose patents have expired have generic equivalents on the market.<sup>11</sup>

The Hatch-Waxman Act is compromise legislation<sup>12</sup> enacted to balance the competing interests of promoting innovation and the discovery of brand name drugs while at the same time fostering the development and market entry of lower cost alternatives.<sup>13</sup> The Act achieved these laudable goals by (1) creating mechanisms for patent holders to protect and enforce their rights; and (2) expediting the FDA approval process for, among other things, generic drugs. To address the concerns of patent holders, the Act restored to the patent holder at least a portion of the patent term lost due to the patent holder's inability to market its patented drug while awaiting FDA approval.<sup>14</sup>

Generic drug companies also received important benefits that facilitate expedient FDA approval for generic drugs. First, they were permitted to rely on the safety and efficacy data of the brand name drug and, therefore, were only required to demonstrate that the generic drug is bioequivalent to the brand name drug.<sup>15</sup> This obviously makes it significantly less expensive for a generic manufacturer to bring a new drug to market. Second, the statute created a safe harbor against patent infringement for activities undertaken to obtain FDA approval to combat the *de facto* patent term extension that patent holders received while generic companies obtained FDA approval.<sup>16</sup>

Section 271(e)(1) of the United States Code created the infringement exemption that eliminated *de facto* patent term extension. Specifically, it provides that:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product ... solely for uses reasonably related to the development and submission of

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<sup>9</sup> See, e.g., *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>10</sup> H.R. REP. NO. 98-857, pt. I, at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2650.

<sup>11</sup> Pharmaceutical Research and Manufacturers Association, *Ten Misconceptions About Pharmaceutical Patent Litigation*, at <http://www.phrma.org/mediaroom/press/releases///16.07.2002.457.cfm> (July 16, 2002).

<sup>12</sup> Those familiar with the legislative process might point out that any legislation is the result of compromise. Pharmaceutical companies, however, are known to be particularly active in lobbying circles, as these companies have much to gain through favorable legislative treatment.

<sup>13</sup> *Andrex Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

<sup>14</sup> 35 U.S.C. § 156 (2000).

<sup>15</sup> 21 U.S.C. § 355(j)(2)(A)(iv) (2000).

<sup>16</sup> 35 U.S.C. § 271(e).

information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>17</sup>

This safe harbor provision was enacted to overrule the Federal Circuit’s decision in *Roche Products, Inc. v. Bolar Pharmaceutical Company*.<sup>18</sup> In that case, Roche held a patent for flurazepam hydrochloride, the active ingredient in its successful prescription sleeping pill marketed under the name Dalmane.<sup>19</sup> Bolar sought to market a generic version of Dalmane when Roche’s patent expired.<sup>20</sup> To this end, Bolar obtained five kilograms of flurazepam hydrochloride from a foreign manufacturer to conduct the necessary tests and gather information required for FDA approval.<sup>21</sup> Roche sued Bolar alleging patent infringement and sought to enjoin Bolar from using the flurazepam hydrochloride until after the expiration of its patent.<sup>22</sup> The district court held that Bolar’s intended use of the patented compound was not an infringement because the federally mandated use was experimental and *de minimis*.<sup>23</sup>

On appeal, Roche challenged the district court’s finding and argued that use of a patented drug to obtain FDA approval constituted an infringing use.<sup>24</sup> Bolar argued that its intended use fell under the experimental use exception and, if not, then a new exception to infringement should be created because public policy favored expedient entry of generic drugs into the market after a patent’s expiration.<sup>25</sup> The Federal Circuit found Bolar’s use was an infringement contemplated by the plain language of the patent statute.<sup>26</sup> Such use did not fall under the experimental use exception, according to the Federal Circuit, because this exception was not intended “[t]o allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”<sup>27</sup> With regard to Bolar’s plea to have the judiciary create a new exception for uses related to FDA testing, the court properly declined to legislate from the bench.<sup>28</sup> Instead, the court correctly invited Congress to create such an exception, if one should exist.<sup>29</sup>

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

<sup>18</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>19</sup> *Id.* at 860.

<sup>20</sup> *Id.*

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

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 860–61.

<sup>24</sup> *Id.* at 860.

<sup>25</sup> *Id.* at 862.

<sup>26</sup> *Id.* at 861. “It is well-established, in particular, that the use of a without either manufacture or sale, is actionable . . . [because] [s]ection 271(a) prohibits, on its face, any and all uses of a patented invention.” *Id.*

<sup>27</sup> *See id.* at 863.

<sup>28</sup> *See id.* at 863–64.

<sup>29</sup> *Id.* at 864. At the same time, two bills were pending before Congress dealing with societal and economic problems concerning the patent holder’s loss of a portion of the patent term due to FDA approval and the need to promote faster marketing of generic drugs. *Id.*; *see also* H.R. 3605, 98th Cong. (1983); S. 1306, 98th Cong. (1983).

## II. THE COMMON LAW EXPERIMENTAL USE EXCEPTION

The experimental use exception originates from Justice Story's opinion in the 1813 decision of *Whittemore v. Cutter*.<sup>30</sup> This judicially created doctrine stems from the rationale that "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>31</sup> The experimental use defense continued to evolve and by 1861 the law was "well-settled ... that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement [was] not an infringement of the rights of the patentee."<sup>32</sup>

The experimental use exception received narrow interpretation from its inception forward. Cases within the last thirty years have further narrowed the defense.<sup>33</sup> In *Madey v. Duke University*, the Federal Circuit ruled that the safe harbor provision did not exempt business conduct, regardless of the commercial or noncommercial implications of such conduct.<sup>34</sup> The Federal Circuit came close to pronouncing the experimental use exception dead, stating that the defense was "very narrow and strictly limited ... to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry...."<sup>35</sup> The court further held that the profit or non-profit status of the alleged infringer was not determinative.<sup>36</sup>

The *Madey* decision debunked the myth that educational institutions and nonprofit research entities were exempt from infringement under the experimental use exception, and created confusion regarding the potential infringement of pure research activities. After *Madey*, most practitioners felt that the experimental use defense was no longer a viable noninfringement defense.

## III. PRE-INTEGRA JUDICIAL INTERPRETATION OF § 271(e)(1)

### A. The Supreme Court's Broad Interpretation of § 271(e)(1)

The Supreme Court addressed the safe harbor provision in *Eli Lilly & Co. v. Medtronic, Inc.*, where it affirmed a Federal Circuit decision that expanded the safe

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<sup>30</sup> 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>31</sup> *Id.* at 1121.

<sup>32</sup> *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

<sup>33</sup> *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (finding that tests, demonstrations, and experiments for FDA approval are solely commercial and consistent with the alleged infringer's legitimate business and thus do not fall under the experimental use exception) (overruled by statute on other grounds); *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976) (finding the United States government was not entitled to the experimental use defense because the government's use of patented helicopters for testing purposes was consistent with the government's legitimate business even though the government did not expect any commercial benefits from such use).

<sup>34</sup> *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

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

<sup>36</sup> *Id.*

harbor to include medical devices subject to FDA approval.<sup>37</sup> In so doing, the Supreme Court admonished Congress for the poor libretto of the safe harbor provision by stating that “[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.”<sup>38</sup>

The Supreme Court rejected Eli Lilly’s contention that the safe harbor applied only to drugs. The Court noted that “the phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.”<sup>39</sup> The Court reasoned that Congress could have chosen a phrase other than “patented invention” or additional limiting language in the safe harbor provision to so limit the statute, but did not do so.<sup>40</sup> Further, the statutory phrase “a Federal law which regulates the manufacture, sale or use of drugs” did not support Eli Lilly’s argument. To the contrary, the Court stated that such language was consistent with “an entire statutory scheme of regulation” and thus it was more natural to read the phrase to include any use reasonably related to regulation under the Federal Food, Drug, and Cosmetic Act (“FDCA”), including uses of medical devices.<sup>41</sup>

Without a clear statutory meaning or strong evidence that Congress intended to limit the safe harbor to drugs only, the Supreme Court resorted to the structure of the Hatch-Waxman Act as a whole to guide its interpretation of § 271(e)(1). On the one hand, § 156 specifically granted a patent term extension to drugs, medical devices, food additives and color additives thereby eliminating the distortion at the front-end of the patent term.<sup>42</sup> On the other hand, § 271(e)(1) granted a safe harbor against infringement of patented inventions “for uses reasonably related to the development and submission of information under a Federal law” thereby eliminating the patent term distortion occurring after the patent expires.<sup>43</sup> The Court reasoned that Congress would not have given drugs and medical devices the advantages of § 156 while only giving drugs the disadvantages of § 271(e)(1).<sup>44</sup> This statutory symmetry rationale bolstered the Court’s holding that medical devices are entitled to the benefits of § 271(e)(1).

Even though the Supreme Court’s decision in *Eli Lilly* did not define the activities exempted from infringement, it set the tone for future judicial decisions concerning § 271(e)(1) by disfavoring a literal word-for-word analysis of the safe harbor language and favoring a broader, policy-based reading of § 271(e)(1).

### *B. The Changing Interpretations of § 271(e)(1) by the Lower Courts*

Early cases evaluating § 271(e)(1) focused on the phrase “solely for uses reasonably related” to FDA approval to narrowly construe the scope of the safe

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<sup>37</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

<sup>38</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990).

<sup>39</sup> *Id.* at 665 (citing 35 U.S.C. § 100 (a) which provides that “[w]hen used in this titled unless the context otherwise indicates . . . [t]he term ‘invention’ means invention or discovery.”).

<sup>40</sup> *Id.* at 667–68.

<sup>41</sup> *Id.* at 667.

<sup>42</sup> 35 U.S.C. § 156 (2000).

<sup>43</sup> *Id.* § 271(e)(1).

<sup>44</sup> *Eli Lilly*, 496 U.S. at 672–73. The Supreme Court expanded the scope of § 271(e)(1) even further than the Federal Circuit to include food additives and color additives. *Id.*



harbor provision. In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, for example, Genentech was not exempted from infringement for its uses that reasonably related to FDA approval because those uses also related to the preparation of a European patent application and the development of a process for commercial-scale production.<sup>45</sup> According to that court, the multiple purposes of Genentech's use obviated § 271(e)(1) protection. Similarly, in *Ortho Pharmaceutical Corporation v. Smith*, the district court found that test data submitted to the FDA but used for the additional purpose of promotional and marketing activities removed the relevant drug from safe harbor protection.<sup>46</sup> The courts in those cases limited the safe harbor provision to "uses" that are "solely" "reasonably related" to FDA approval.<sup>47</sup>

This trend started to shift towards a broader construction in subsequent cases, as courts focused more on the "reasonably related" language of the safe harbor provision.<sup>48</sup> In these cases, the Federal Circuit and district courts departed from prior decisions and noted that the underlying purpose of the infringer's activities was irrelevant to the applicability of § 271(e)(1).<sup>49</sup> The Federal Circuit, for example, recognized that the statutory language of "solely for *uses* reasonably related" was not the same thing as "solely for *purposes* reasonably related."<sup>50</sup> Such analysis resulted in a broad expansion of the protections afforded by the safe harbor of § 271(e)(1).

In *Intermedics, Inc. v. Ventritex, Co.*, Intermedics argued that Ventritex could not assert a § 271(e)(1) defense because Ventritex intended to commercialize its product prior to the expiration of Intermedics' patents.<sup>51</sup> The district court held that the availability of § 271(e)(1) depended upon the "actual use" of the alleged infringer and not the "purpose" of the use.<sup>52</sup> Instead, the court held that the proper inquiry was whether the allegedly infringing activities were reasonably related to FDA approval and used the following test for determining the applicability of § 271(e)(1):

[W]ould it have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product? If the answer is yes, it should not matter that other reasonable persons might have concluded that FDA approval could be secured even without the information in question.<sup>53</sup>

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<sup>45</sup> 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) *modified on other grounds*, 678 F. Supp. 1429 (N.D. Cal. 1988); 707 F. Supp. 1547 (N.D. Cal. 1989), *aff'd in part, rev'd in part, vacated in part and remanded on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991).

<sup>46</sup> 18 U.S.P.Q.2d 1977, 1992 (E.D. Pa. 1990).

<sup>47</sup> *Id.*

<sup>48</sup> *See, e.g.*, *Elan Transdermal, Ltd. v. Cygnus Therapeutic Sys.*, 24 U.S.P.Q.2d 1926, 1932–33 (N.D. Cal. 1992).

<sup>49</sup> *See, e.g.*, *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523–25 (Fed. Cir. 1992); *AbTox, Inc v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997); *Nexell Therapeutics, Inc. v. AmCell Corp.*, 199 F. Supp. 2d 197, 203–05 (D. Del. 2002).

<sup>50</sup> *See, e.g.*, *Telectronics Pacing Sys.*, 982 F.2d at 1523–25.

<sup>51</sup> 775 F. Supp. 1269, 1273 (N.D. Cal. 1991).

<sup>52</sup> *Id.* at 1275.

<sup>53</sup> *Id.* at 1280–81.

Under this test, Ventritex’s activities were subject to the safe harbor of § 271(e)(1). The Federal Circuit affirmed and held that reliance on § 271(e)(1) was “not precluded by manifestation of an intent to commercialize upon FDA approval.”<sup>54</sup> This objective test acknowledges the inherent unpredictability in the FDA approval process and shields the accused infringer from that unpredictability. The Federal Circuit cited with approval the test set out by the district court in *Intermedics*, in the case of *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*<sup>55</sup>

In *Telectronics*, the Federal Circuit considered Telectronics’ argument that Ventritex’s demonstrations of its defibrillator to non-physicians at medical conferences were non-exempt activities and thus infringing.<sup>56</sup> The Federal Circuit rejected this argument. Ventritex demonstrated its defibrillator to obtain clinical investigators and, therefore, those activities were reasonably related to obtaining FDA approval.<sup>57</sup> The fact that non-physicians saw the defibrillator as part of a non-sale demonstration, according to the Federal Circuit, was “merely incidental and of minimal import.”<sup>58</sup>

The Federal Circuit continued its trend towards a broader interpretation of the safe harbor provision in *AbTox, Inc. v. Exitron Corporation*, holding that an alleged infringer need not have applied for FDA approval to avail itself of safe harbor protection.<sup>59</sup> There, Exitron and MDT conducted tests that provided data needed for FDA approval of Exitron’s plasma sterilizer.<sup>60</sup> AbTox contended that the purpose of these tests was to promote the plasma sterilizer to customers and to induce MDT to purchase the patent rights to the device.<sup>61</sup> The Federal Circuit again refused to consider the purpose of the tests and instead analyzed the use of the data generated by the test. The Federal Circuit held that the underlying purpose, intent, or alternative uses of an infringer’s activities were irrelevant under § 271(e)(1) and it was improper to “look to the underlying purposes or attendant consequences of the activity ... as long as the use [was] reasonably related to FDA approval.”<sup>62</sup>

*AbTox* is also instructive because it confronted the “novel” question of whether Class I and Class II medical devices can benefit from the safe harbor of § 271(e)(1). *Eli Lilly* only involved Class III medical devices, which are subject to the benefits of § 156.<sup>63</sup> Class II medical devices are not subject the benefits of § 156.<sup>64</sup> The Federal Circuit evaluated *Eli Lilly’s* broad holding that the safe harbor applies to any use reasonably related to regulatory approval under the FDCA against the Court’s rationale that Congress intended statutory symmetry between §§ 156 and 271(e)(1).<sup>65</sup> The Federal Circuit followed the Supreme Court’s broader holding even though the Federal Circuit’s ruling was in apparent conflict with the Supreme Court’s rationale

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<sup>54</sup> *Intermedics, v. Ventritex*, 26 U.S.P.Q.2d 1524, 1528 (Fed. Cir. 1993).

<sup>55</sup> *Telectronics Pacing Sys., Inc.*, 928 F.2d at 1525 n.5.

<sup>56</sup> *Id.* at 1522–23.

<sup>57</sup> *Id.* at 1523.

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

<sup>59</sup> 122 F.3d 1019 (Fed. Cir. 1997).

<sup>60</sup> *Id.* at 1027.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 1030.

<sup>63</sup> *Id.* at 1029.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 1028–29.

in *Eli Lilly*.<sup>66</sup> The Federal Circuit interpreted *Eli Lilly* to prefer, but not mandate, statutory symmetry between §§ 156 and 271(e)(1).<sup>67</sup>

In *Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc.*, Rhone-Poulenc Rorer (“RPR”) held a patent claiming a process for making taxol and four intermediates generated during the process.<sup>68</sup> Bristol used the intermediates in experiments that were part of its research and development activities aimed at developing taxol analogs.<sup>69</sup> Bristol initiated its taxane research and development program in an attempt to discover a new, more active drug that could replace taxol upon the expiration of RPR’s patent.<sup>70</sup> Bristol conducted hundreds of tests with the patented intermediate for the purpose of synthesizing taxol analogs and identifying possible drug candidates from those analogs.<sup>71</sup> The patented intermediates were also used to develop a structure-activity relationship database for the synthesized analogs.<sup>72</sup> If an analog showed the desired activity, then the analog was tested further to determine if additional development activities were warranted.<sup>73</sup> If continued development was warranted, a process for making the compound would be developed and further optimization, synthesis, testing, analysis, and scale up would be performed.<sup>74</sup> Ultimately, Bristol submitted two analogs for FDA approval.<sup>75</sup>

RPR argued that § 271(e)(1) should only apply after the filing of an application with the FDA or after identification of a particular drug candidate in a filing.<sup>76</sup> Bristol argued that the exemption should apply to all activities reasonably related to an actual or possible FDA application.<sup>77</sup> Bristol further contended that it would be nonsensical for the exemption to apply only upon the filing of an FDA application because the exemption would never be reached as the underlying preliminary research could not be performed.<sup>78</sup>

The district court agreed with Bristol and held that § 271(e)(1) protected all research (including synthesizing potential new drug candidates), initial testing of new candidates, and further testing of new candidates to inform a decision of whether or not the new candidates should be pursued.<sup>79</sup> The court relied on the *Intermedics* test and indicated that there must be “a decent prospect that the ‘use’ in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the process by which the FDA would

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<sup>66</sup> *Id.* at 1029.

<sup>67</sup> *Id.* “Moreover, the [Supreme] Court explicitly accepted a statutory interpretation ‘in which a patentee will obtain the advantage of the [section 156] extension but not suffer the disadvantage of the [section 271(e)(1)] noninfringement provision, and others in which he will suffer the disadvantage without the benefit.’” *Id.*

<sup>68</sup> *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, Civ. No. 95-8833, 2001 WL 1512597, at \*1 (S.D.N.Y. Nov. 28, 2001).

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

<sup>70</sup> *Id.* at \*4.

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

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

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.* at \*6.

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

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

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at \*7.

decide whether to approve the product.”<sup>80</sup> According to the court, the decent prospect must relate to the potential that the information being generated might be relevant to FDA approval and not the likelihood that the information will be submitted to the FDA.<sup>81</sup> The Federal Circuit never reviewed this decision because it was not appealed.

Interestingly, the holdings in *Bristol-Myers, AbTox* and *Intermedics* all arguably could not stand under the new test announced by the Federal Circuit in *Integra*. We next discuss the Federal Circuit’s ruling in that case.

#### IV. *INTEGRA LIFESCIENCES I, LTD. v. MERCK KGAA*

In *Integra*, the patentee, Integra, owned patents relating to a RGD peptide sequence that promoted blood vessel growth and beneficial cell adhesion to substrates by interacting with beta receptors on cell surface proteins.<sup>82</sup> Dr. David Cheresh, a scientist and professor at The Scripps Research Institute (“Scripps”) discovered that by blocking avB3 receptors, one could inhibit the formation of new blood vessels.<sup>83</sup> Inhibiting the formation of new blood vessels showed promise as a means of halting tumor growth by starving tumor cells.<sup>84</sup>

Merck recognized the potential importance of Dr. Cheresh’s discovery and offered, in 1988, to fund additional research by Dr. Cheresh and Scripps in this area. The agreement contemplated beginning clinical trials with a drug candidate within three years.<sup>85</sup> In 1997, after years of research, the Scripps research team chose the best new drug candidate for clinical development, one separately developed by Merck.

Integra learned of the Scripps-Merck agreement and, believing that angiogenesis research was a commercial project that infringed its RGD-related patents, offered Merck licenses to the patents in suit.<sup>86</sup> When settlement discussions broke down, Integra filed suit against Merck, Scripps and Dr. Cheresh.<sup>87</sup>

##### A. *The Majority Opinion*

At trial, the District Court for the Southern District of California held that the § 271(e)(1) exemption did not apply to the Merck-sponsored research.<sup>88</sup> The Federal Circuit affirmed, focusing its analysis on the legislative intent. The Federal Circuit noted that “[t]he House Committee that initiated the safe harbor provision expressly

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<sup>80</sup> *Id.* (quoting *Intermedics, Inc. v. Ventritex, Co.*, 775 F. Supp. 1273, 1280 (N.D. Cal. 1991)).

<sup>81</sup> *Id.*

<sup>82</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 862 (Fed Cir. 2003), *amended by*, No. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (Fed. Cir. July 10, 2003).

<sup>83</sup> *Id.* at 863. The scientific term for the process of generating new blood vessels is angiogenesis. *Id.*

<sup>84</sup> *Id.* at 863.

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

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 863–64.

described the pre-market approval activity as ‘a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.’<sup>89</sup> Such an infringement would thus only be “de minimis.”<sup>90</sup> The Federal Circuit concluded that because § 271(e)(1) is limited to activities that are “solely [for uses] reasonably related to the development and submission of information to the FDA’... [t]he exemption ‘cannot extend at all beyond uses with the reasonable relationship specified in § 271(e)(1).’<sup>91</sup> Moreover, the court stated that the statutory safe harbor provision “simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”<sup>92</sup>

Additionally, the court concluded that extending § 271(e)(1) to encompass new drug development would not limit the exemption to instances of de minimis infringement.<sup>93</sup> Furthermore, the Federal Circuit recognized that a broad interpretation of § 271(e)(1) would “effectively vitiate the exclusive rights of patentees owning biotechnology tool patents.”<sup>94</sup> The court stated that an expansive reading of the safe harbor provision “would swallow the benefit of the Patent Act for some categories of biotechnological inventions.”<sup>95</sup> Finally, the court held that as a result of its analysis, the Merck-sponsored research was not embraced by the language and context of the safe harbor provision.<sup>96</sup>

### B. *The Dissent*

Judge Newman’s strong dissent explained that pursuant to the “common-law” research exemption, the subject matter of patents might be studied “in order to understand it, or to improve upon it, or to find a new use for it, or to modify or ‘design around’ it.”<sup>97</sup> Otherwise, a patentee might capitalize upon the fear of an infringement suit and stop the “advancement of technology” in a certain field.<sup>98</sup> In Judge Newman’s view, Merck took a patented product that was of no value in Integra’s hands (because Integra failed to develop a product) and improved it.<sup>99</sup> According to Judge Newman, the fact that profits were the ultimate goal or hope of a research effort should not preclude that effort from the safe harbor exemption.<sup>100</sup> “The better rule is to recognize the exemption for research conducted in order to understand or improve upon or modify the patented subject matter....”<sup>101</sup>

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<sup>89</sup> *Id.* at 865.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 866.

<sup>92</sup> *Id.* at 867.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

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

<sup>96</sup> *Id.* at 868.

<sup>97</sup> *Id.* at 875 (Newman, J. dissenting). Judge Newman was referring to the “experimental use” exception, which creates an exemption for patent infringement solely for research, academic or experimental purpose. *See* *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>98</sup> *Integra Life Sciences I, Ltd. v. Merck KGaA*, 331 F.3d. 860, 875 (2003).

<sup>99</sup> *Id.* at 876.

<sup>100</sup> *Id.* at 876.

<sup>101</sup> *Id.*

Although Judge Newman agreed with the majority that § 271(e)(1) does not embrace the “development and identification of new drugs,” she reasoned that Merck’s research either was exempt exploratory research or was immunized by the statutory safe harbor provision.<sup>102</sup> “It would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited.”<sup>103</sup> Judge Newman concluded that such an arrangement “would defeat the purposes of both exemptions; the law does not favor such an illogical outcome.”<sup>104</sup>

## V. ARGUMENTS PRESENTED TO THE SUPREME COURT

### A. Merck’s Position on the Merits

In its opening brief on the merits, Merck provided the Supreme Court with background information on the process for developing drugs and the FDA approval process. Merck described basic research as relating to the agents that cause disease and how the body reacts to that disease.<sup>105</sup> Merck further described this basic research as including the screening of thousands of compounds (or a select number of compounds based on an educated guess) to identify possible drugs that might interact with biochemical targets to combat a particular disease.<sup>106</sup> If any of these screenings yield promising results, then the drug innovator determines whether or not to proceed with FDA approval, which consists of two phases: pre-clinical and clinical.<sup>107</sup> The pre-clinical phase involves generation data to satisfy the FDA that the drug is safe and effective for human clinical trials.<sup>108</sup> *In vitro* and/or animal testing may be part of the pre-clinical phase.<sup>109</sup> After gathering the needed data, a drug innovator submits an Investigational New Drug Application (“IND”).<sup>110</sup> If the FDA is satisfied with the pre-clinical information, clinical trials may begin. Upon completion of clinical trials, a New Drug Application (“NDA”) is submitted to the FDA.<sup>111</sup>

With this description of the drug development and FDA approval process as a backdrop, Merck argued that the safe harbor provision is broad and covers a wide range of *in vitro* and animal testing. Merck contended that Congress intended § 271(e)(1) to be broadly applied—the words Congress chose exempted *any* experiment from infringement “so long as it would be reasonable for the researcher to believe the experiment could generate information of a sort the FDA considers at

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<sup>102</sup> *Id.* at 877.

<sup>103</sup> *Id.* at 877.

<sup>104</sup> *Id.*

<sup>105</sup> Brief for Petitioner, at 7, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 823 (2005) (No. 03–1237).

<sup>106</sup> *Id.* at 6–7.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

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

some point in its role as regulators of drugs.”<sup>112</sup> Merck noted that Congress did not limit the exemption to generic drugs or to a particular type of FDA application.<sup>113</sup>

Merck then attacked the Federal Circuit’s decision as converting the express language of § 271(e)(1) into an exemption solely for clinical tests, i.e., exempting research for the NDA but not research for the IND.<sup>114</sup> Merck argued that the NDA application itself belies the Federal Circuit’s holding because even the NDA considers nonclinical data.<sup>115</sup> Further, Congress directed the FDA to consider information beyond that submitted with the NDA including any other information before the FDA, such as the pre-clinical data submitted with the IND.<sup>116</sup> If Congress intended the safe harbor provision to apply only to clinical testing, according to Merck, it could have expressly stated such.<sup>117</sup>

Merck next argued that the Federal Circuit improperly limited its decision based on the legislative history of § 271(e)(1). First, Merck noted that Congress never intended to limit the exemption to generic drugs and the Supreme Court has already addressed this issue.<sup>118</sup> Second, Merck argued that applying the exemption to pre-clinical research does not extend § 271(e)(1) to all general biomedical research.<sup>119</sup> Merck contended that the statement in the legislative history that the exemption was only a de minimis encroachment on a patent holder’s rights meant that the FDA exemption does not take away a patent holder’s commercial market exclusivity.<sup>120</sup> Merck argued the infringement is de minimis even if the exemption reaches all the way down the chain of experimentation.<sup>121</sup> However, Merck noted that the Supreme Court need not go that far in this case because all of its research was pre-clinical research.<sup>122</sup> Merck relied on an FDA paper describing the medical product development spectrum as follows: basic research, prototype design or discovery, pre-clinical development, clinical development, FDA filing/approval & launch preparation.<sup>123</sup>

In short, Merck logically argued that all of the research in the case involved experiments aimed at producing information reasonably related to an eventual submission to the FDA and was, therefore, exempt from infringement.<sup>124</sup>

### *B. United States’s Amicus Curiae Brief on Merits*

The United States filed an amicus curiae brief in support of Merck and argued that the FDA exemption “protects all activities that are undertaken in the course of attempting to develop a particular drug and are reasonably related to the

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<sup>112</sup> *Id.* at 28–29.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.* at 30.

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

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 32–36.

<sup>119</sup> *Id.* at 36.

<sup>120</sup> *Id.* at 36–37.

<sup>121</sup> *Id.* at 37.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.* at 37–38.

<sup>124</sup> *Id.* at 43–50.

development of the types of information that would be relevant to” an IND or NDA.<sup>125</sup> The United States contended that Congress expressly contemplated, as evidenced by certain provisions of the United States Code, that pre-clinical studies would be submitted to the FDA and thus entitled to exempt status.<sup>126</sup> The United States further noted that the FDA has considered this type of information.<sup>127</sup> For example, the regulations contemplate and the FDA typically considers as part of an IND, pre-clinical research including animal or *in vitro* pharmacological and toxicological studies as well as pre-clinical effectiveness studies.<sup>128</sup> Additionally, the United States contended that the Federal Circuit’s decision was inconsistent with the Supreme Court’s decision in *Eli Lilly*.<sup>129</sup>

The United States also argued that the Federal Circuit’s decision was based on an inaccurate view of Congress’ intent in enacting the safe harbor provision.<sup>130</sup> According to the government’s brief, Congress was concerned with eliminating delayed market entry, not simply the facilitation of a generic drug market.<sup>131</sup> The United States pointed out that while the Federal Circuit issued an errata sheet indicating that the scope of § 271(e)(1) was not limited to generic drugs, the decision still appeared to be limited to generic drugs and appeared to exclude pre-clinical studies prepared for an IND from the safe harbor.<sup>132</sup>

The United States further argued that not all research is exempted by § 271(e)(1), but, rather, only research reasonably related to the development and submission of information to the FDA.<sup>133</sup> For example, basic exploratory research is not covered.<sup>134</sup> The United States contended that the exemption protected experiments: (1) “undertaken in the course of an attempt to develop a particular drug,” and (2) “reasonably related to the development of the types of information that would be relevant to an IND or NDA.”<sup>135</sup>

The government’s brief further contended that the exemption applies when a researcher moves beyond basic research and initiates efforts to develop a particular drug because if those efforts are successful it is foreseeable that an IND will be submitted.<sup>136</sup> Stated differently, the exemption should protect research aimed at “[d]eveloping a substance with specific characteristics in order to achieve a specific objective” (*e.g.*, cure a specific disease).<sup>137</sup> The United States argued that the Federal Circuit’s limitation of the exemption, enabling it to work after the identification of the best drug candidate, is improper because a researcher typically does not identify the best drug candidate until after screening potentially hundreds or thousands of

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<sup>125</sup> Brief for United States as Amicus Curiae Supporting Petitioner, at 8, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 823 (2005) (No. 03–1237).

<sup>126</sup> *Id.* at 9–10.

<sup>127</sup> *Id.* at 10.

<sup>128</sup> *Id.* at 10–12.

<sup>129</sup> *Id.* at 14.

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

<sup>131</sup> *Id.* at 13–14.

<sup>132</sup> *Id.* at 15.

<sup>133</sup> *Id.* at 15–16.

<sup>134</sup> *Id.* at 17.

<sup>135</sup> *Id.* at 16.

<sup>136</sup> *Id.* at 16–17.

<sup>137</sup> *Id.* at 17.



compounds.<sup>138</sup> The Federal Circuit's interpretation, the United States argued, eviscerated the exemption for new drugs because new drugs would always infringe as a new drug cannot be first identified without screening.<sup>139</sup> The United States also argued that studies on compounds not selected for an IND or NDA are protected by the exemption because they directly relate to the determination of what compound is the most promising and because unselected compounds are often included in the IND as being relevant to safety and efficacy.<sup>140</sup>

The United States contended that “[m]ost if not all of the work conducted during the relevant stages of drug development” was exempted from infringement.<sup>141</sup> The United States approvingly cited *Nexell Therapeutics, Inc. v. AmCell Corporation* and endorsed the view that activities are not covered by the exemption “when they have no objectively reasonable application toward obtaining FDA approval.”<sup>142</sup> The United States reasoned that the IND and NDA require similar types of information, but the FDA has not required specific types of experiments for an IND.<sup>143</sup> Courts prior to the Federal Circuit's decision in this case granted applicants considerable leeway in determining what types of studies to conduct because of the lack of specific FDA guidance.<sup>144</sup> The United States reasoned that the holdings of those courts reflected the better standard, and a more restrictive approach could harm public health by deterring additional research on safety and efficacy.<sup>145</sup> The United States further argued, as supported by prior case precedent, that the exemption should not be limited to experiments actually submitted as part of an IND or NDA, and that intent should play no role in the determining the exemption's applicability.<sup>146</sup> According to the United States, a subjective standard would chill the very research Congress sought to encourage.<sup>147</sup>

Finally, the United States argued that the Federal Circuit erred by artificially narrowing the FDA exemption to attempt to protect research tools.<sup>148</sup> The United States, like Merck, argued that it is unclear whether the plain language of § 271(e)(1) covers research tools and whether Congress intended to exempt the use of research tools from infringement.<sup>149</sup> The United States then noted that even if research tools are exempted, the consequences of such exemption may not be as severe as the Federal Circuit indicated as research tools have uses outside of the stages of development protected by the FDA exemption.<sup>150</sup>

### *C. Integra's Brief in Opposition*

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<sup>138</sup> *Id.* at 18.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 19.

<sup>141</sup> *Id.* at 21.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.* at 22–23.

<sup>146</sup> *Id.* at 24.

<sup>147</sup> *Id.* at 25.

<sup>148</sup> *Id.* at 28.

<sup>149</sup> *Id.* at 29.

<sup>150</sup> *Id.* at 30.

Integra has not filed its opposition brief on the merits yet. Below is a discussion of the positions advanced by Integra in its opposition to the petition for certiorari, which will likely be similar to the positions they advance in their opposition brief on the merits.

Integra argued that Merck’s general biomedical research should not be exempt from infringement under § 271(e)(1) because the research was too far removed from research that is reasonably related to FDA approval.<sup>151</sup> Integra further argued that Merck is trying to rewrite the safe harbor of § 271(e)(1)—an FDA exemption—into a general biomedical research exemption.<sup>152</sup> The interpretation advocated by Merck, according to Integra, would eliminate the protections afforded under the patent laws for biotechnology tool patents.<sup>153</sup>

Integra contends that the Federal Circuit’s decision was not limited to generic drugs and the plain language of the statute required a proximate, not attenuated, relationship to FDA approval.<sup>154</sup> If Congress had intended to exempt general biomedical research, Integra argued, Congress could have easily drafted the exemption broadly and not required a reasonable relationship to regulation under a federal law.<sup>155</sup> Integra also contended that the Federal Circuit’s decision was consistent with the legislative history because Congress intended to remedy the patent term distortion that occurred after the expiration of the patent by allowing an insubstantial interference with the patent holder’s rights during the patent’s term.<sup>156</sup> A broad interpretation of the safe harbor provision, so the argument goes, would be a substantial interference with patent rights, thereby contravening congressional intent.

As a final point, Integra argued that there was no evidence of record to suggest that research has or will stop as a result of the Federal Circuit’s decision.<sup>157</sup>

## VI. THE SUPREME COURT AND THE FUTURE

### *A. Two Schools of Thought on § 271(e)*

Analyzing the cases leading up to *Integra* and the majority and dissenting opinions in that case, there appear to be two diametrically opposite schools of thought on the safe harbor provision. Indeed, the cases preceding the *Integra* decision present an interpretation of the safe harbor provision that is difficult to square with the Federal Circuit’s reasoning in *Integra*. Interestingly, however, both schools of thought rely heavily on policy arguments to support their interpretation. The Supreme Court will likely examine the policy implications encompassed by the

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<sup>151</sup> Brief in Opposition of Integra Lifesciences I, Ltd. and The Burnham Institute, at 15, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 823 (2005) (No. 03–1237)

<sup>152</sup> *Id.* at 11.

<sup>153</sup> *Id.* at 3.

<sup>154</sup> *Id.* at 8–10.

<sup>155</sup> *Id.* at 12.

<sup>156</sup> *Id.* at 12–14.

<sup>157</sup> *Id.* at 15.

safe harbor provision and will likely weigh in with their interpretation of what Congress intended when § 271(e)(1) was enacted.

Ironically, both schools of thought argue that the opposing view will frustrate public policy by discouraging the development of new drugs. One school of thought on the scope of the safe harbor provision, reflected by the majority opinion in *Integra*, concludes that a *narrow* interpretation of the statutory language will facilitate biotechnological research.<sup>158</sup> Proponents of a narrow safe harbor provision argue that a broadened safe harbor would leave many patentees uncompensated for their hard work, which would serve as a disincentive to develop new technology.<sup>159</sup> Proponents of narrow safe harbor protection also posit that if companies are dissuaded from publicly disclosing new technologies through the patent process, this will violate the legislative intent of § 271(e).<sup>160</sup>

Similarly, proponents of a broad interpretation of § 271(e)(1), reflected in Judge Newman's dissent in *Integra*, argue that the doctrine should be interpreted in a way to maximize the development of important new therapeutic products.<sup>161</sup> As Judge Newman noted in her dissent, the Federal Circuit's ruling creates a "limbo" period between exploratory research and FDA submission that can subject a researcher to patent infringement. According to proponents of a broad safe harbor provision, the Federal Circuit's narrow interpretation of § 271(e) will stagnate, and not promote, the development and identification of new drugs due to the possibility of infringement allegations. This, in turn, would frustrate public policy and hamper scientific research.

These opposing interpretations have continued to be vocalized since the enactment of § 271(e)(1) more than twenty years ago and reflects the original interests of competing drug companies in construing the Hatch-Waxman Act.<sup>162</sup> Both sides present compelling arguments regarding not only the language of the statute and legislative history, but also the public policy implications supporting their proposed outcome. The Supreme Court will now have a chance to strike an equitable balance between these competing views.

### B. The Supreme Court's Dilemma

Anybody who watched the 2004 Presidential debates knows that access to pharmaceuticals has become a crucial issue in American politics. The public has, for some time now, seen insurance rates increasing and the costs of many drugs are

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<sup>158</sup> See generally Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 11 (2001).

<sup>159</sup> See Rich J. Warburg et al., *Patentability and Maximum Protection of Intellectual Property in Proteomics and Genomics*, 22 BIOTECHNOLOGY L. REP. 264, 270–73 (2003) (arguing that if the district courts' broad interpretation of the safe harbor provision was correct, companies would be better served by protecting its technology as a trade secret rather than seeking patent protection).

<sup>160</sup> See *id.*

<sup>161</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons Biomedical Research*, 280 SCI. 698, 699 (1998).

<sup>162</sup> ORRIN HATCH, *SQUARE PEG: CONFESSIONS OF A CITIZEN SENATOR* 70–81 (Basic Books 2002) (Senator Hatch explains how during the legislative process discussions between the generic drug manufacturer representatives and the "brand companies" were often heated).

getting beyond the means of ordinary citizens, particularly the elderly. This presents a challenging landscape for the Court to address a statute that was initially intended to make low-priced pharmaceutical drugs more accessible, while still preserving patent rights.

While it is difficult to project what the Supreme Court will do in response to the issues raised in the *Integra* case, the Federal Circuit’s analysis is troubling primarily because the plain language of the statute does not require a showing that the new product would actually be submitted to the FDA. By focusing on activities related to the submission of information to the FDA, the court failed to explain *how* suitable drug candidates could be identified without immunized pre-clinical research and testing. Before a generic manufacturer can present a drug candidate to the FDA for approval, it must find the best generic equivalent worthy of FDA approval. What remains unexplained by the Federal Circuit’s majority opinion in *Integra* is how a generic manufacturer can identify suitable candidates for FDA consideration without conducting experiments, and thus infringing others’ patents. By strictly limiting what experiments will qualify for protection under the safe harbor provision, the Federal Circuit’s ruling will force generic manufacturers to find new ways to create generic equivalents—an alternative that could not only be extremely costly but unrealistic. This contravenes a primary goal of Congress in enacting the Hatch-Waxman Act.

The Supreme Court will also have to consider the broad scope it afforded § 271(e)(1) in the *Eli Lilly* case, albeit in a different context. It will be difficult for the Court to reconcile a broad interpretation regarding the type of activities captured by the safe harbor provision with a narrow interpretation of actual activities protected by the provision.

Judge Newman’s dissent harmonizes the difficulties created by the Federal Circuit’s ruling by bridging activities and providing continuous exemption under a combination of the experimental use and safe harbor exemptions. Specifically, Judge Newman argued that in cases requiring FDA approval, the experimental use exemption should flow seamlessly into the safe harbor exemption so as to avoid the awkward period where a researcher would be liable for infringement when the activities directly before and after that period are exempt from infringement.<sup>163</sup>

Acceptance of Judge Newman’s approach would not only lend clarity to researchers and serve as an incentive for future research projects, but it would eliminate the nebulous line of where research ends and efforts to gain FDA approval begin. In simple terms, it is unreasonable to permit a competing researcher free use of patented subject matter for initial research and also during the process of seeking FDA approval, but *not* in the gray area between these two stages. This trap for the unwary should be eliminated or researchers simply will not assume the risks.

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<sup>163</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989). Judge Newman stated: [T]he territory that the Scripps/Merck research traversed, from laboratory experimentation to development of data for submission to the FDA, was either exempt exploratory research, or was immunized by § 271(e)(1). It would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed.

In order to clarify this area of law for practitioners and the research community, the Supreme Court should interpret the safe harbor provision of the Hatch-Waxman Act, as Congress intended, to permit *all stages of research and development* related to efforts to obtain FDA approval, from initial research to the final stages of FDA submission, to be exempt from infringement. Another question to be answered by the Supreme Court is whether the safe harbor provision is intended only to provide protection for commercial entities, or whether it was intended to immunize the research community as well.<sup>164</sup> The answers to these questions are extremely important to an industry, to academia, and to consumers.

The Supreme Court's discussion of the Hatch-Waxman Act and the safe harbor provision promises to be an interesting discussion of the balance between patent rights and the right to identify and develop new drugs.

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<sup>164</sup> Another possibility is that the Supreme Court will defer to Congress, affirming the Federal Circuit opinion below and holding that Congress alone should determine whether a court's ruling violates the intended scope of a statute. The potential ramification of Congressional intervention is beyond the scope of this article.