

***MERCK v. INTEGRA LIFESCIENCES: THE  
SUPREME COURT PROTECTS THE USE OF  
PATENTED COMPOUNDS IN PRECLINICAL STUDIES***

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**MERCK v. INTEGRA LIFESCIENCES – THE  
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**I. INTRODUCTION**

According to the Pharmaceutical Manufacturers Association, it takes ten to fifteen years and costs \$800 million, on average, to bring a new medicine to market.<sup>2</sup> Because of the extensive time period required, pharmaceutical companies try to start this process as soon as possible, even when patented compounds in activities related to the federal regulatory process are used. On June 13, 2005, the U.S. Supreme Court unanimously held in *Merck KGaA v. Integra Lifesciences I, Limited*, that under a Patent Act exemption from infringement,<sup>3</sup> the use of patented compounds in pre-clinical studies are protected as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments provide necessary and relevant information.<sup>4</sup> The exemption from infringement applies, according to the Court, even if the patented compounds do not themselves become the subject of an FDA submission.<sup>5</sup> This article will analyze this important Supreme Court decision and its implication.

**II. DRUG PATENTS AND THE REGULATORY EXEMPTION  
SAFE HARBOR**

The Congress shall have power . . . [t]o  
promote the progress of science and useful  
arts, by securing for limited times to authors  
and inventors the exclusive right to their  
respective writings and discoveries . . . .<sup>6</sup>

Pursuant to this power, Congress has enacted patent law under which a patent holder is protected against an infringer who, without authority, makes, uses, offers to sell, or sells any patented invention.<sup>7</sup> A common law

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<sup>2</sup> PHRMA Intellectual Property Overview, <http://www.phrma.org/issues/intprop/> (last visited June 18, 2005).

<sup>3</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>4</sup> *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2383 (2005).

<sup>5</sup> *Merck KGaA*, 125 S. Ct. at 2384 n.8.

<sup>6</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>7</sup> 35 U.S.C. § 271(a) (2000).

research exemption, also called the traditional experimental use exemption, articulated by Justice Story nearly two hundred years ago, recognized the importance of experimentation, and allowed certain unauthorized uses of patented inventions if the uses promoted the goals of the patent system.<sup>8</sup> An experimental use exemption to infringement allows experimentation on the invention as well as basic research on philosophical experiments.<sup>9</sup>

In 1984, the Court of Appeals for the Federal Circuit prohibited the experimental use exemption for clinical trials that utilized a patented medicine.<sup>10</sup> In *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, the clinical trials were used in an attempt to obtain regulatory approval of the generic equivalent of the patented medicine.<sup>11</sup> Congress legislatively overruled this narrow interpretation by enacting the Hatch-Waxman Act,<sup>12</sup> as a part of the Drug Price Competition and Patent Term Restoration Act of 1984.<sup>13</sup> The Hatch-Waxman Safe Harbor provision states that it is not an act of infringement to make, use, offer to sell, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>14</sup>

In 1990, the U.S. Supreme Court extended this regulatory exemption to medical devices in *Eli Lilly and Company v. Medtronic, Incorporated*.<sup>15</sup> The Court focused on the statutory language of “solely for the purposes reasonably related to the development and submission of information under a Federal law . . .”<sup>16</sup> and held that Medtronic’s testing of an implantable cardiac defibrillator for which Eli Lilly had patents was exempt from infringement.<sup>17</sup>

The statutory regulatory safe harbor, related to, but distinct from the common law experimental use exemption,<sup>18</sup> has had broad court

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<sup>8</sup> See *Whittemore v. Cutter*, 29 F. Cos. 1120 (C.C.D. Mass. 1813). See also Steven P. Caltrider and Paula Davis, *The Experimental Use Defense: Post-Madey v. Duke and Integra Lifesciences I, Ltd. v. Merck KGaA*, 86 J. PAT. & TRADEMARK OFF. SOC’Y. 1011, 1012 (2004) (citing *Sawin v. Gould*, 21 F. Cos. 554 (C.C.D. Mass. 1813)).

<sup>9</sup> Brief of Intellectual Property Professors as Amici Curiae in Support of Neither Party at \*5, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, No. 03-1237 (2005).

<sup>10</sup> *Roche Products, Inc. v. Bolar Pharmaceutical co., Inc.*, 733 F.2d 858, 860 (Fed. Cir. 2002).

<sup>11</sup> *Roche*, 733 F.2d 858, 863 (Fed. Cir. 2002) (stating that the common law experimental use exception was very narrow and strictly limited). See also *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002).

<sup>12</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>13</sup> Pub. L. No. 98-417, 98 Stat. 1585; codified at 21 U.S.C. § 355 (2000), 35 U.S.C. § 271(e) (2000).

<sup>14</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>15</sup> *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990).

<sup>16</sup> *Id.* at 665 (quoting 35 U.S.C. § 271(e)(1)).

<sup>17</sup> *Id.* at 669.

<sup>18</sup> Brief for Amicus Curiae The American Intellectual Property Law Association in Support of Neither Party at \*22, *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct.

interpretation;<sup>19</sup> while the common law exemption has been more narrowly construed.<sup>20</sup>

### III. *MERCK v. INTEGRA*

This case lies at the intersection of patent law and the drug approval process . . . .<sup>21</sup>

In the mid-1980's, Dr. Ruoslahti and Dr. Pierschbacher discovered that peptides which contain the Arg-Gly-Asp (RGD) amino acid sequence, promote cell adhesion by interacting with receptors on cells' surfaces.<sup>22</sup> This cell adhesion was studied in the hope that it could lead to pharmaceutical products that could "prevent angiogenesis -- the production of new blood vessels -- in patients suffering from [such medical problems as] tumors, diabetic retinopathy, rheumatoid arthritis, and inflammatory bowel disease."<sup>23</sup>

Dr. Ruoslahti and Dr. Pierschbacher formed Telios Pharmaceuticals, and obtained patents regarding their discovery.<sup>24</sup> In 1988, U.S. patent number 4,789,734 was obtained for a method of isolating cell surface receptors utilizing a short peptide sequence.<sup>25</sup> In 1988, the U.S. patent number 4,792,525 was also obtained for the tetra peptide X-Arg-Gly-Asp-R-Y, which has an industrial application as an invention useful in surgery and therapeutic reconstruction and treatment of injuries.<sup>26</sup> In 1989, patent number 4,879,237 was issued for the use of peptides in control of cell attachment and detachment.<sup>27</sup> In 1991, patent number 4,988,621 was issued

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2372, No. 03-1237 (2005). This group contends that the common law exemption has no bearing on interpreting the statutory exemption. *Id.*

<sup>19</sup> See generally *Eli Lilly*, 496 U.S. 661.

<sup>20</sup> See generally *Roche Products, Inc. v. Bolar Pharmaceutical co., Inc.*, 733 F.2d 858, 858 (Fed. Cir. 2002).

<sup>21</sup> Brief for Respondents on the Merits at \*1, *Merck KGaA*, 125 S. Ct. 2372, No. 03-1237 (2005).

<sup>22</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 96-CV-1307-B(AJB), 2004 U.S. Dist. LEXIS 20725 at \*5 (S.D. Cal. Sept. 7, 2004).

<sup>23</sup> *Id.* at \*5-6.

<sup>24</sup> *Id.* at \*1. Telios raised venture capital to continue the research, which was licensed. *Id.*

<sup>25</sup> U.S. Patent No. 4,789,734 (issued Dec. 6, 1988), available at <http://www.uspto.gov> (last visited June 18, 2005). The claim is for a substantially purified cell surface receptor capable of binding to a peptide containing the RGD amino acid sequence. *Id.* (paraphrasing Claims).

<sup>26</sup> U.S. Patent No. 4,792,525 (issued Dec. 20, 1988), available at <http://www.uspto.gov> (last visited June 18, 2005). The portion of the term of the patent after March 25, 2003 was disclaimed. *Id.*

<sup>27</sup> U.S. Patent No. 4,879,237 (issued Nov. 7, 1989), available at <http://www.uspto.gov> (last visited June 18, 2005). This invention is founded on the discovery that compounds in which the active ingredient consists essentially of the RGD peptide possesses unique and unexpected cell detachment characteristics. *Id.* (paraphrasing Summary

for peptides in cell detachment and aggregation.<sup>28</sup> Then, in 1997, patent number 5,695,997 was issued for a tetra peptide,<sup>29</sup> useful in surgery and therapeutic reconstruction and treatment of injuries.<sup>30</sup>

In 1988, Merck KGaA (Merck), a German pharmaceutical company,<sup>31</sup> entered into an agreement (1988 agreement), with the Scripps Research Institute to fund specified projects, including the research of Dr. Cheresch. Dr. Cheresch discovered that blocking certain receptors inhibits angiogenesis, which generates new blood vessels, could halt tumor growth. This agreement ended in 1994.<sup>32</sup>

In 1994, Merck informed Scripps that it would not be renewing the 1988 agreement. Later that year, Dr. Cheresch published an article on his RGD peptide research. In that same year, Telios contacted Merck to reach a licensing agreement for the use of the RGD peptides covered by Telios' patents, and as a result Merck became interested in acquiring Telios and its RGD patents.<sup>33</sup>

In 1995, Integra acquired Telios for \$20 million; and in that same year, Merck and Scripps entered into another agreement (1995 agreement).<sup>34</sup> Under the 1995 agreement Merck agreed to fund Dr. Cheresch's research on the anti-angio genesis properties of RGD peptides at Scripps, and conduct the necessary research experiments to meet the FDA requirements for clinical research on EMD 66203, which, in a test tube, jammed the receptors

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of the Invention). The significance of this invention was deemed far-reaching and of considerable importance in research, diagnostics, and cell biology. *Id.* (paraphrasing Discussion).

<sup>28</sup> U.S. Patent No. 4,988,621 (issued Jan. 29, 1992), available at <http://www.uspto.gov> (last visited June 18, 2005). The significance is similar to the 1257 patent. *Id.* (paraphrasing Discussion). See also *supra* note 26.

<sup>29</sup> U.S. Patent No. 5,695,997 (issued Dec. 9, 1997), available at <http://www.uspto.gov> (last visited June 18, 2005).

<sup>30</sup> *Id.* at Industrial Application. This invention contemplates a new poly peptide which alters cell attachment activities to various substances. *Id.* (paraphrasing Summary of the Invention).

<sup>31</sup> Merck KGaA is a publicly traded German company, consisting of a network of nearly 200 companies in over 50 countries. Merck develops, makes, and sells pharmaceutical and chemical products for global consumption, and is active in cancer research. Merck is the ancestor to U.S. drug company Merck & Co., now EMG. Hoover's Company Records, <http://www.hoover.com/Merck-kgaa/--ID 5808900--/free-co-factsheet.xhtml> (last visited June 7, 2005).

<sup>32</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 96-CV-1307-B(AJB), 2004 U.S. Dist. LEXIS 20725 at \*8 (S.D. Cal. Sept. 7, 2004). Scripps is a non-profit corporation; Dr. Cheresch is a tenured professor at Scripps known for his study of compounds including the amino acid sequence RGD used to inhibit the growth of blood vessels. *Integra Lifesciences I, Inc. v. Merck KGaA*, C.L. No.: 96-CV-1307-TW(AJB), 1998 U.S. Dist. LEXIS 23215 at \*2-3 (S.D. Cal. Dec. 22, 1998).

<sup>33</sup> *Integra Lifesciences I, Ltd.*, 2004 U.S. Dist. LEXIS 20725 at \*6-8. Merck sent Telios a letter of intent concerning the possible license in 1994. Part of the due diligence process was a minimal schedule by Telios of future RGD peptide development. *Id.* at \*7.

<sup>34</sup> *Id.* at \*7.

on the surface of blood cells,<sup>35</sup> which had application in cancer treatments. Scripps's research led to the development of derivations of EMD 66203, EMD 85189, and EMD 121974, and experiments were conducted on these derivations to see if they were candidates for human trials.<sup>36</sup>

In 1996, Merck informed Telios/Integra that it was no longer interested in entering into licensing agreements for the RGD patents.<sup>37</sup> Telios/Integra filed suit against Merck, Scripps, and Dr. Cheresch for patent infringement.<sup>38</sup> Merck answered that it was protected by the statutory safe harbor,<sup>39</sup> and that the RGD patents were invalid.<sup>40</sup>

The district court granted Merck's motion for summary judgment of invalidity of claim two of patent number 4,988,621.<sup>41</sup> Following a jury trial, a federal district court ruled that Merck infringed on all five of Integra's patents.<sup>42</sup> Further, the statutory safe harbor did not exempt Merck.<sup>43</sup> The jury awarded a royalty of \$15,000,000.<sup>44</sup>

On appeal, the Court of Appeals for the Federal Circuit had to decide whether the pre-clinical research done at Scripps and funded by Merck is exempt from liability under the statutory safe harbor.<sup>45</sup> In this case, the experiments did not supply information to the FDA, but rather identified the best drug for further clinical testing.<sup>46</sup> The appeals court examined the statutory language of the safe harbor, which limits the activities to those "solely for uses reasonably related to the development and submission of information" to the FDA.<sup>47</sup> The appeals court interpreted the word "solely" to constrain the statutory safe harbor, stating that the exemption "cannot extend at all beyond uses with the reasonable relationship specified."<sup>48</sup>

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<sup>35</sup> *Id.* at \*7-9. Dr. Cheresch also succeeded in reversing tumor growth in chicken embryos with EMD 66203. *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2377-78 (2005).

<sup>36</sup> *Integra*, 2004 U.S. Dist. LEXIS 20725 at \*10.

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

<sup>38</sup> *Id.* Initially, the plaintiffs alleged only that patent No. 4,792,525 was infringed. In 1997, an amended complaint alleging that patents numbered 4,988,621, 4,789,734, and 4,879,237 were also infringed. In 1998, a supplemental complaint was filed that patent number 4,695,997 was also infringed. *Integra*, 1998 U.S. Dist. LEXIS 23215 at \*4.

<sup>39</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>40</sup> *Integra*, U.S. Dist. LEXIS 20725 at \*10.

<sup>41</sup> *Ingra Lifesciences, I, Ltd. v. Merck KGaA*, C.L. No.: 96-CV-1307 TW (AJB), 1999 U.S. Dist. LEXIS 10380 at \*22 (S.D. Cal. Feb. 9, 1999). Every element of claim two had been disclosed in the prior art, and the plaintiff's own 1984 article in *Nature* anticipated, and thus invalidated, Claim two. *Id.*

<sup>42</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 at \*2 (Fed. Cir. June 6, 2003).

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at \*12.

<sup>46</sup> *Id.*

<sup>47</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>48</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 at \*14 (Fed. Cir. June 6, 2003).

According to the appeals court, the district court did not err in the interpretation of the safe harbor, because the focus of the entire exemption is the provision of information to the FDA.<sup>49</sup>

The appeals court, however, agreed with Merck that the royalty was not supported by substantial evidence.<sup>50</sup> The case was remanded for further factual analysis and calculation of damages.<sup>51</sup>

In her dissent, Judge Newman focused on both the goal of financial incentive and the goal of adding to the body of knowledge.<sup>52</sup> While the common law research exemption is a limited exception,<sup>53</sup> the statutory safe harbor “took up where the research exemption left off.”<sup>54</sup> The dissent would have held the defendants’ activities exempt or immune from infringement.<sup>55</sup>

On remand, Merck alleged that the evidence supported a reasonable royalty of about \$40,000, while Integra argued that the evidence supported the full \$15 million royalty.<sup>56</sup> The district court awarded Integra \$6.375 million,<sup>57</sup> under patent law.<sup>58</sup>

Merck requested, and the Supreme Court granted, certiorari,<sup>59</sup> to decide the issue of whether the use of patented inventions in preclinical research, which are not ultimately included in the submission to the FDA, are exempted from infringement by the statutory safe harbor of 35 U.S.C. §

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<sup>49</sup> *Id.* at \*14, 19. See generally, B. Scott Gidson, *How Safe is the Harbor? Considering the Economic Implications of Patent Infringement in Section 271(e) (12) Analysis*, 82 WASH U.L.Q 1169 (2004).

<sup>50</sup> *Integra*, 2003 U.S. App. LEXIS 27796 at \*33.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at \*35. The goal of adding to the body of knowledge includes the right to conduct research without waiting for the expiration of the patent. *Id.*

<sup>53</sup> *Id.* at \*40.

<sup>54</sup> *Integra*, 2003 U.S. App. LEXIS 27796 at \*52.

<sup>55</sup> *Id.* See generally Elizabeth Corasiniti, *Devastation of the Safe Harbor Provision of 35 U.S.C. § 271(e)(1): The Federal Circuit’s Shifting Protection to Patentees*, 26 T. JEFFERSON L. REV. 421 (2004); Melissa J. Alcorn, *A Tale of Peptide and Lasers: Is Integra Lifesciences I, Ltd v. Merck KGaA the End of the Experimental Use Defense for Biomedical Innovation, or Does § 271(e)(1) of the Patent Act Save the Day?* 57 OKLA. L. REV. 381 (2004).

<sup>56</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 96-CV-1307-B(AJB), 2004 U.S. Dist. LEXIS 20725 at \*4 (S.D. Cal. Sept. 7, 2004).

<sup>57</sup> *Id.* at \*5. The appellate court ordered the district court to consider the following:

(1) the proper timing the court should use in calculating the reasonable royalty, (2) how other license agreements may influence the reasonable royalty calculation in the instant case, (3) other factors which influence the calculation of a reasonable royalty, and (4) the reasonable royalty that Merck would have paid Telios/Integra had the parties entered into a licensing agreement for the RGD Peptide technology.

*Id.* at \*11-12.

<sup>58</sup> 35 U.S.C. § 284 (2000) (granting damages to compensate for infringement, no less than a reasonable royalty).

<sup>59</sup> *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2383 (2005). The Court of Appeals for the Federal Circuit denied a rehearing, and rehearing *en banc* *Integra Lifesciences I, Ltd. v. Merck KGaA*, C.L. No.: 02-1052, 02-1065, 2003 U.S. App. LEXIS 26547 (Fed. Cir. Dec. 3, 2003).

271(e)(1).<sup>60</sup> The U.S. Supreme Court unanimously held on June 13, 2005, that they are exempt.<sup>61</sup>

Justice Scalia authored the Court's opinion. First, the Court reviewed the FDA's regulatory process under the Federal Food, Drug, and Cosmetic Act (FDCA),<sup>62</sup> since this act is a law which regulates the manufacture, use, or sale of drugs under the statutory safe harbor.<sup>63</sup> A maker of a generic drug need only file an abbreviated new drug application (ANDA) with the FDA.<sup>64</sup> The maker of the generic drug does not have to show that the drug is safe and effective in preclinical and clinical studies, only that the drug has the same active ingredients and is the bio-equivalent of an approved drug.<sup>65</sup> For new drugs, however, the drug maker must submit an investigational new drug application (IND) that must describe preclinical tests, including tests on animals, sufficient to justify clinical tests.<sup>66</sup> Then, the drug maker must submit a new drug application containing full reports of investigations to show whether the drug is safe and effective.<sup>67</sup>

The Court started its analysis by stating that it is apparent from the statutory text of the exemption that infringement extends to all uses of patented inventions reasonably related to the development and submission of any information under the FDCA.<sup>68</sup> This would include, according to the Court, preclinical as well as clinical studies, because the statute did not exclude information from the exemption based upon the stage of research in which it was developed.<sup>69</sup>

The Supreme Court then examined the reasons that the Court of Appeals for the Federal Circuit used to support its conclusion that the safe harbor did not protect Scripp's RGD peptide research.<sup>70</sup> First, the Merck-funded experiments did not supply information to the FDA, but rather identified the best drug candidate to submit from further clinical testing under the FDA processes.<sup>71</sup> Second, the Court of Appeals concluded that the

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<sup>60</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>61</sup> *Merck KGaA*, 125 S. Ct. at 2383-84.

<sup>62</sup> 21 U.S.C. §§ 301-397 (2000).

<sup>63</sup> 35 U.S.C. § 271(e)(1) (2000).

<sup>64</sup> 21 U.S.C. § 355(j) (2000).

<sup>65</sup> 21 U.S.C. § 355(j)(2)(A) (2000).

<sup>66</sup> 21 U.S.C. § 355(i) (2000).

<sup>67</sup> 21 U.S.C. § 355(b)(1) (2000). This must also include all preclinical and clinical studies on efficiency, toxicity, and pharmacological properties. 21 C.F.R. § 314.50(d) (2005).

<sup>68</sup> *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2380 (2005) (citing *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990)).

<sup>69</sup> *Id.* at \*17. Respondents argued that preclinical studies on a drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably submitted to the FDA, and are thus outside the scope of the exemption; the Court disagreed. *Id.* at 2381. The respondents further argued that the experiments were not entitled to the exemption because they weren't performed in conformance with the FDA's good laboratory practices. *Id.* This agreement was also rejected by the Court as being overly narrow. *Id.* at 2382.

<sup>70</sup> *Id.* at 2382-83.

<sup>71</sup> *Id.* at 2382 (citing *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003)).

safe harbor does not exempt all experimental activity which could lead to an FDA approval process.<sup>72</sup>

Concerning the second reason, the Court generally agreed that not every basic scientific research project on a compound is reasonably related to the development and submission to the FDA.<sup>73</sup> However, the Court rejected the arguments that the safe harbor does not apply to either experimentation on drugs that is not the subject of an FDA submission, or the use of patented compounds in experiments not submitted to the FDA.<sup>74</sup> Hence, the safe harbor is sufficiently broad to cover both situations, under certain conditions.<sup>75</sup>

Concerning the first reason, a researcher cannot initially know whether any given experimentation will result in a successful compound that will eventually result in an application to the FDA.<sup>76</sup> Thus, using patented compounds in experiments which do not result in a submission of information to the FDA does not automatically result in an infringement.<sup>77</sup> Examining the statutory text,<sup>78</sup> the Court concluded that Congress exempted all uses of potential compounds reasonably related to the process of developing information for submission under any federal law regulating the manufacture, use, and distribution of drugs.<sup>79</sup> This, according to the Court, leaves room for experimentation and failure; so long as the drug maker has a reasonable basis for believing that a compound may work.<sup>80</sup> Hence, the judgment of the Court of Appeals for the Federal Circuit was vacated, and the case remanded.<sup>81</sup>

#### IV. CONCLUSION

The U.S. Supreme Court unanimously held in 2005 that the Patent Act's safe harbor for using a patented invention solely for uses reasonably related to the development and submission of information under federal law

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<sup>72</sup> *Id.* at 2382 n.7 (citing *Integra*, 331 F.3d at 867).

<sup>73</sup> *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2382 n.7 (2005).

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

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 2383. This is particularly true at the preclinical stage. *Id.*

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

<sup>78</sup> See 35 U.S.C. § 271(e)(1) (2000).

<sup>79</sup> *Merck KGaA v. Integra Lifesciences I, Limited*, 125 S. Ct. 2372, 2383 (2005).

<sup>80</sup> *Id.* Congress did not limit the Safe Harbor to the development of information to submit to the FDA or to an ANDA submission for a generic drug. *Id.* The Court thus agreed with the government as amicus curiae. *Id.* The government contended that the court of appeals, relying on legislative history, erred by limiting the safe harbor to clinical studies. Brief for Amicus Curiae United States at \*4, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237). Ironically, the U.S. supported the German pharmaceutical company Merck KGaA's arguments over the arguments of Integra. Brief for Petitioner, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237).

<sup>81</sup> *Merck KGaA*, 125 S. Ct. at 2384.

regulating the manufacture, use, or sale of drugs<sup>82</sup> includes preclinical research which is not ultimately included in a submission to the FDA, if there is a reasonable basis to believe the compound may work.<sup>83</sup> This victory has been hailed as a win for drug giants.<sup>84</sup> This aids pharmaceutical companies in legally experimenting on potentially new drugs, and is a win for those pharmaceutical companies actively researching new pharmaceuticals while using existing patents of others. For Merck,<sup>85</sup> however, with revenues of nearly \$8 billion in 2004, the \$15 million reasonable royalty initially assessed would have resulted in less than two-tenths of one percent of annual revenues.

Medical patients, and in this case, cancer patients are also possible winners in this battle, as they may be able to receive life-saving treatment sooner. While patents are respected,<sup>86</sup> research may also progress on potentially new patentable compounds, striking a balance between the competing goals of the patent systems to encourage innovation while ultimately improving the public's welfare in the long run. With 600,000 new cases of solid tumor cancer in the U.S. each year,<sup>87</sup> there is hope that drugs such as the one submitted to the FDA by Merck based on research done under Integra's five patents will be marketed sooner to potential aid cancer victims.<sup>88</sup>

As Merck is a German corporation conducting research in the U.S.,<sup>89</sup> this decision may further aid the U.S. pharmaceutical industry by allowing firms to continue to conduct preclinical and clinical research in the U.S., rather than conducting research abroad in countries with different patent systems.<sup>90</sup> Finally, the Trade-Related Aspects of Intellectual Property Rights Agreement, part of the World Trade Organization Agreement, allows its members to provide limited exception to the exclusive rights conferred by a patent, so long as the exceptions do not reasonably conflict with the normal exploitation of the patent, or unreasonably prejudice the legitimate interest of

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<sup>82</sup> See 35 U.S.C. § 271(e)(1) (2000).

<sup>83</sup> *Merck KGaA*, 125 S. Ct. at 2383.

<sup>84</sup> Bernard Wysocki Jr. and Jess Bravin, *Justices Grant Exemption from Patent Infringement for Early Stage. Merck Court Win to Aid Drug Giants*, WALL ST. J., June 14, 2005, at A3.

<sup>85</sup> See *supra* note 30.

<sup>86</sup> Merck pointed out in its brief to the U.S. Supreme Court that it would not market the drug it discovered until the patent had expired, nor had Merck done so in the past. Brief for Petitioner at \*3, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237).

<sup>87</sup> Joint Appendix at \*69a, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, No. 03-1237 (2005).

<sup>88</sup> This author's father was a cancer victim. Consequently, this author has enormous sympathy for all cancer victims and their families, and may be biased towards aiding new treatments.

<sup>89</sup> See *supra* note 30.

<sup>90</sup> Allison Ladd, *Integra v. Merck: Effects and the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 353 (2005).

the patent owner.<sup>91</sup> This safe harbor, as interpreted by the Court, seems to fully comply with this global agreement.

Thus, the *Merck* decision grants pharmaceutical companies and others the right to use patented compounds in certain preclinical studies and maintains a vibrant environment in the U.S. for drug testing, which has the potential to aid consumers and patients. In so holding, this important decision strikes the correct balance.

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<sup>91</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1995, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 30.