

# ACCEPTING EXCEPTIONS?: A COMPARATIVE APPROACH TO EXPERIMENTAL USE IN U.S. AND GERMAN PATENT LAW

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## I. INTRODUCTION AND PROBLEM OUTLINE

“I love fools’ experiments. I am always making them.”<sup>1</sup>

*A. The Benefit of Comparisons*

Stating that an apple is a green or red fruit and a wristwatch is not a fruit does not convey anything about either object. As such comparisons are neither inherently useful nor per se justified as a scholarly or practical endeavor. A comparative approach to U.S. patent law has to be conducted with a suitable counterpart. “There are no less than 42 legal systems in the world, and comparison has traditionally focused on three major legal families . . . namely the civil law system, common law system and socialist system.”<sup>2</sup> Instead of comparing the United States, a common law country, with socialist countries that are heavily decreasing in numbers and do not provide for patent systems that acknowledge substantial private property rights, the United States should be compared with either European Union law in general or with a civil law country.

Because this Article deals with an infringement issue, it should be noted that pursuant to Article 64(3) of the European Patent Convention even infringement of a European patent (save infringement of national patents) is to be dealt with by national law.<sup>3</sup> Thus, only the Member States of the European Union are left as suitable objects for a comparison.

From the academic point of view, the United States could be compared to Portugal, Iceland, or Germany. Although one has to agree with the proposition that the “[d]iscussion[] of the goals of comparative law often draw[s] an overly sharp distinction between its practical and its scientific aims,”<sup>4</sup> and that the scientific benefit of each of the comparisons above would be of equal value, a comparison with one of the major European trade partners has to be considered the more

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1. LIFE AND LETTERS OF CHARLES DARWIN: INCLUDING AN AUTOBIOGRAPHICAL CHAPTER (Francis Darwin ed., 1897), *reprinted in* JOHN BARTLETT, FAMILIAR QUOTATIONS: A COLLECTION OF PASSAGES, PHRASES, AND PROVERBS TRACED TO THEIR SOURCES IN ANCIENT AND MODERN LITERATURE 445 (Justin Kaplan ed., 18th ed. 1992) (1855).

2. PETER DE CRUZ, COMPARATIVE LAW IN A CHANGING WORLD 3 (1995).

3. Convention on the Grant of European Patents, Oct. 5, 1973, art. 64(3), 1065 U.N.T.S. 199, 274, *available at* <http://www.european-patent-office.org/legal/epc/>.

4. MARY ANN GLENDON ET AL., COMPARATIVE LEGAL TRADITIONS IN A NUTSHELL 5 (2d ed. 1999).

practical, and thus, more useful approach. Transatlantic patent disputes, namely infringement suits, arise more frequently with one of the European trading partners.

### B. U.S. and German Patent Law

Although it would go well beyond the scope of this Article and may be worthy of treatment in a thesis discussing and comparing the history of both legal systems, a brief introductory remark on the genesis of both patent law systems seems appropriate. Contrary to usual common law thinking that legal principles were developed in Great Britain and later adopted and modified by the United States, the United States conceived of the need for patent protection sooner than Germany.

President George Washington signed the Patent Act into law as early as 1790;<sup>5</sup> whereas in eighteenth century Germany, a patent system was not felt to be a pressing need, at least not by the administration of the economically and politically most important state of Prussia.<sup>6</sup> According to an 1853 survey conducted by the Royal Prussian Ministry of Trade and Commerce that was administered to the Prussian District Governments (Bezirksregierungen) and Chambers of Trade, thirty-one out of forty-seven of these participants voted against the implementation of a patent protection scheme.<sup>7</sup> Consequently, a uniform German patent act did not exist until 1877<sup>8</sup> and it was not until 1936<sup>9</sup> that the statute acknowledged the inventor, and not the patent applicant, as the sole legitimate proprietor.<sup>10</sup>

### C. The Problem

With the parties to the comparison being established, the discussion will now turn to the specific problem at issue.

It is the very dilemma of patent law, or as Professor Cornish put it, the “innate conflict in the objects for which patent systems exist,”<sup>11</sup> that

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5. Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

6. At the respective time, before the foundation of the Deutsche Reich in 1871, Germany did not even exist as a nation, but consisted of a loose collection of small states.

7. See Wolfgang Pfaller, *Das Patentgesetz von 1877*, <http://www.people.freenet.de/patentgeschichte/1877.htm> (last visited Dec. 1, 2005).

8. Patentgesetz [Patent Act], May 25, 1877 RGBl. I at 501 (F.R.G.).

9. Patentgesetz [Patent Act], May 5, 1936 RGBl. II at 117 (F.R.G.).

10. See Paul Bluhm, *Die Entstehung des ersten gesamtdeutschen Patentgesetzes* [Genesis of the First Uniform German Patent Act], 1952 GRUR 341, 341–46.

11. William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC 735, 735 (1998).

lays out the background for the specific issue: striking a balance between the “attempt to promote interest in research while at the same time conferring the exclusivity incentive that a patent grants to the inventor.”<sup>12</sup>

Abstractly speaking, he who seeks to invent something new will always build upon what his predecessors have invented. One could thus argue that it is both logical and in the public interest to allow experiments with a patented invention. This very abstract statement, however, oversimplifies the problem. It does not address whether inventors may feel discouraged from refining and elaborating on an invention. For example, in the pharmaceutical industry, mandatory prerequisites for marketing a new product may chill invention. In the case of pharmaceuticals, extensive testing is required before a new compound will be admitted to the market by the Federal Drug Administration (FDA). With a development cost of approximately \$500 million for a new medicinal product,<sup>13</sup> considerable economic interests are at stake. Thus, numerous questions demand a more thorough analysis in the quest for the adequate legal treatment of experiments. Are pharmaceuticals a special case? Does that change the general policy on experimenting? What is this policy? What should it be? If privileges for experimental conduct are to be granted, what should be deemed an experiment as opposed to plain infringement?

Safeguarding the effect of a patented invention in the “global world”<sup>14</sup> of today means not only being aware of domestic regulations but also considering foreign regulations that affect patent protection and the scope of possible defenses to infringement claims. The defense that has been most frequently discussed and that is, at least for the pharmaceutical industry, likely to be the crucial point of practical patent protection is the safe harbor for experimental use, a provision that seeks to reconcile the problem mentioned above.

Article 28(1) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement states that a patent shall confer on its owner the right “to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing [the]

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12. Tanuja V. Garde, *The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104*, 35 IIC 241, 242 (2004).

13. Dr. Harvey E. Bale, Jr., *Encouragement of New Clinical Drug Development: The Role of Data Exclusivity 1* (2000), [http://www.ifpma.org/documents/NR643/DataExclusivity\\_2000.pdf](http://www.ifpma.org/documents/NR643/DataExclusivity_2000.pdf).

14. This is, of course, strictly speaking a pleonasm, yet used here to emphasize the increasingly intertwined and international character of business and commerce in the world.

product.”<sup>15</sup> Thus, third-party activities with a patent are, generally speaking, not “experiments,” but plain infringement.<sup>16</sup>

As an exception to that rule, Article 30 of the TRIPS states that “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably . . . prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties.”<sup>17</sup> The wording suggests that Member State legislators who are willing to address the issue have more than one option for complying with TRIPS.

#### D. Further Procedure of Analysis and Terminology

Speaking of “experimental use,” two basic constructions have to be kept separate. One is experimental use as an *exception to public use* under 35 U.S.C. § 102(b),<sup>18</sup> and the second is experimental use as a *defense to patent infringement claims*. This form of experimental use is subdivided into *common law* experimental use (a controversial subject) and *statutory* experimental use.

The terminology used for keeping these constructions separate is unfortunately different depending on the authority and sometimes even inconsistent within a single court. The Federal Circuit talks about “the experimental use and *de minimis* exceptions,”<sup>19</sup> thereby obviously characterizing “experimental use *exception*” as the proper term for the exception to the § 102(b) statutory bar and “*de minimis* exception” as the proper term for the experimental use defense to patent infringement claims. The same court also, however, uses the term “experimental use *exemption*” for the latter characterization.<sup>20</sup> Referring to legislative materials, the court pointed out that “[35 U.S.C. § 271(e)(1)] has been coined an ‘exemption’ in the case law, drawing from terminology used in the legislative history.”<sup>21</sup> However, those very materials used the term

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15. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 1125, 1197, art. 28(1) (1994) [hereinafter TRIPS].

16. The issue of the unfortunate terminology in the field of “experimental use” will be addressed in Part I.D.

17. TRIPS, *supra* note 15, at art. 30.

18. 35 U.S.C. § 102(b) (2000).

19. *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

20. *See, e.g., Integra Lifesciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 866 n.3 (Fed. Cir. 2003) (citing *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325–26 (Fed. Cir. 2003)).

21. *Integra*, 331 F.3d at 866 n.3 (citing H.R. REP. NO. 98-857, pt. 2, at 5 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2689)).

“exception”<sup>22</sup> as does the wording of Article 30 of TRIPS.<sup>23</sup> In a recent article, the opposite terminology is suggested: “[t]he experimental use *exemption* to the 35 U.S.C. § 102(b) public use . . . is distinct from the experimental use *exception* to patent infringement.”<sup>24</sup> Prior to *Merck KGAA v. Integra Lifesciences I, Ltd.*,<sup>25</sup> the U.S. Supreme Court referred, like other courts,<sup>26</sup> to the statutory patent infringement defense as the “clinical trial *exemption*.”<sup>27</sup> It emphasized that the exemption was by no means only referring to clinical trials.<sup>28</sup> An issue that will be addressed below.

In this Article, the experimental use *exception* will stand for the 35 U.S.C. § 102(b) public use bar and the experimental use *exemption* will stand for the statutory patent infringement defense. This is not to say that no other terminology is possible. Alternatively, a leading treatise on patent law describes the § 102(b) public use concept as the “experimental use *negation*,”<sup>29</sup> an expression that can also be based on Federal Circuit precedent.<sup>30</sup>

Strictly speaking, the statutory safe harbor should not be referred to as the “experimental use” exception/exemption/negation at all, because the word “experimental” does not correctly characterize the testing activity—not to explore unknown territories, but rather to confirm the bioequivalency of patented drugs. As the British Court of Appeal stated in *Monsanto Co. v. Stauffer Chemical Co.*,<sup>31</sup> trials carried out for the purpose of demonstrating that “the product works as its maker claims were not to be regarded as acts done ‘for experimental

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22. H.R. REP. NO. 98-857, at 5 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2689.

23. *See* TRIPS, *supra* note 15, at art. 30.

24. *See* Michelle Walters, *De Minimis Use and Experimental Use Exceptions to Patent Infringement: A Comment on the Embrex Concurrence*, 29 AIPLA Q.J. 509, 510 n.1 (2001).

25. 125 S. Ct. 2372 (2005).

26. *See, e.g.*, *Datascope Corp. v. Vascular Solutions, Inc.*, 165 F. Supp. 2d 933, 935 (D. Minn. 2001); *Intermedics v. Ventritex, Co.*, 775 F. Supp. 1269, 1272 (N.D. Cal. 1991); Ann K. Wooster, Annotation, *Construction and Application of Hatch-Waxman Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. FED. 487, 524 (2005).

27. *Datascope Corp.*, 165 F. Supp. 2d at 935 (emphasis added); *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

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

29. MARTIN J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 196 (2d ed. 2003) (emphasis added).

30. *See id.* at 204–05 (citing *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1122 (Fed. Cir. 1996)).

31. *Monsanto Co. v. Stauffer Chem. Co.*, [1985] R.P.C. 515, 1987 GRUR INT. 108 (Eng.).

purposes.”<sup>32</sup> If the U.S. Supreme Court itself had not declared the exemption to apply beyond the clinical trials phase, the more accurate wording would be its term, “clinical trial exemption.” Accordingly, for reasons to be discussed in this Article, because this term is not appropriate for the more general German provisions, this term will not be used here. In any event, it is of little benefit to discuss these widely semantic questions at length.

Staying with the unfortunate term “experimental use” for all constructions requires that they all be briefly defined, even though the public use bar is not an issue here. Thereafter, the relevant German provisions on experimental use and its implications will be explained in Part III, followed by a discussion of the differences and similarities between the U.S. and German provisions in Part IV. The conclusion will follow under Part V. A simplified chart outlining the major differences is in the Appendix.

## II. EXPERIMENTAL USE IN U.S. PATENT LAW

### *A. Experimental Use as an Exception to the § 102(b) Statutory Bar*

*Black’s Law Dictionary* defines this form of “experimental-use exception” as “an exception to the public-use statutory bar, whereby an inventor is allowed to make public use of an invention for more than one year when that use is necessary to test and improve the invention.”<sup>33</sup> As early as 1877, the U.S. Supreme Court provided a broad foundation for experimental use in *City of Elizabeth v. American Nicholson Pavement Co.*<sup>34</sup> in which it allowed an inventor of a new road pavement to test it on the open street provided that he retained some form of control.<sup>35</sup> This form of experimental use is not relevant for infringement claims and will not be pursued any further in this Article.

### *B. Common Law Experimental Use Exemption*

The second meaning of experimental use, and the only pertinent one for the purpose of this Article, is a special kind of *de minimis* infringement defense. When talking about common law experimental use, the first question is whether this is an existing concept at all. Judge

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32. *Id.* at 517, 1987 GRUR INT. at 110.

33. BLACK’S LAW DICTIONARY 619 (8th ed. 2004).

34. 97 U.S. 126 (1877).

35. *Id.* at 135–36.

Rader, in his often-cited concurrence in *Embrex, Inc. v. Service Engineering Corp.*, argued that “the Patent Act leaves no room for any *de minimis* or [common law] experimental use excuses for infringement.”<sup>36</sup> Judge Newman, on the other hand, feared that the Federal Circuit’s *Integra* opinion “disapproves and essentially eliminates the [existing] common law research exemption.”<sup>37</sup> Despite Judge Newman’s explicit concerns, this issue has not been addressed by the U.S. Supreme Court’s recent ruling in that case.<sup>38</sup>

As the following discussion will show, “common law *de minimis* infringement”—assuming it does exist—is currently being examined by U.S. courts through a highly theoretical approach. Although such an experimental use exemption was promulgated by the judiciary as early as 1813,<sup>39</sup> an exception focusing on what the Federal Circuit later described as a use performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry” does not constitute a practically applicable defense for the business-oriented players on the global stage of intellectual property.<sup>40</sup>

In simplified terms, one can say that common law requires that “one cannot maintain an action for a wrongdoing where there is no damage.”<sup>41</sup> For example, when no profit ensued from a patent violation, there are presumably no damages.<sup>42</sup> Thus, “the experimental use exception does not protect experiments or tests which have a commercial purpose.”<sup>43</sup> Cases in which courts allowed the alleged infringer to plead such a defense are “relatively rare,”<sup>44</sup> amounting to “five cases in the history of the Republic.”<sup>45</sup> Judge Newman argued that

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36. 216 F.3d at 1352.

37. See *Integra Lifesciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part).

38. *Merck KGAA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 *passim* (2005).

39. See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813). “[I]t 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.” *Id.*

40. *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

41. See *Garde*, *supra* note 12, at 243.

42. See *Byam v. Bullard*, 4 F. Cas. 934 (C.C.D. Mass. 1852) (quoting *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813)).

43. *Ares-Serono, Inc. v. Organon Int’l B.V.*, 862 F. Supp. 603, 608 (D. Mass. 1994).

44. ADELMAN ET AL., *supra* note 29, at 845.

45. David Carney, *Supreme Court Takes Case Involving Research Exemption to Patent Infringement*, TECH. L.J. § 7 (Jan. 7, 2005), <http://www.techlawjournal.com/topstories/2005/20050107.asp> (quoting Judge Rader from an unpublished source).

“philosophical” indeed meant “scientific”<sup>46</sup> and that the wording warrants a broader understanding. This controversy will be discussed in Part V.

The Federal Circuit’s construction of the experimental use exception leaves only non-commercial use, a phenomenon hardly found in practice. Even universities cannot be presumed to be “ivory towers,” detached and separated from profit-oriented thinking, especially after the passage of the Bayh-Doyl Act.<sup>47</sup> In fact, universities are very much in the business of research, and many are generating substantial revenues for experiments or earning considerable royalties from patents in the commercial sector.<sup>48</sup> The Federal Circuit has recently declined to hold that university research is exempt from patent infringement.<sup>49</sup> Reaffirming Judge Newman’s concerns, one scholar observed, “[t]his holding severely limited, to the point of near elimination, the common law experimental use defense.”<sup>50</sup>

This is a valid point considering that Duke University, in its writ of certiorari to the U.S. Supreme Court, stated that private universities could never benefit from experimental use because all of their research is in furtherance of their legitimate business objectives; whereas—although absurd in the eyes of Duke University—commercial enterprises could lawfully engage in simply experimental research.<sup>51</sup> It did not grant certiorari,<sup>52</sup> demonstrating that the point made by Duke University did not significantly concern the U.S. Supreme Court.<sup>53</sup> That

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46. As Judge Newman pointed out in her concurring in part, dissenting in part opinion to *Integra*, the “philosophical” experiment refers to “natural philosophy,” which is commonly understood as “science” today. See Garde, *supra* note 12, at 243 n.10.

47. Pub. L. No. 96-517, 94 Stat. 3015, 3019–28 (1980) (codified as 35 U.S.C. §§ 200–12 (2000)). The Act seeks “to promote collaboration between commercial concerns and nonprofit organizations, including universities.” *Id.*

48. See Ted Agres, *Columbia Patents under Attack*, THE SCIENTIST, July 25, 2003, available at <http://www.the-scientist.com/news/20030725/03>. “Five large biotech and pharmaceutical companies are accusing Columbia University of having illegally extended the life of key DNA patents to maintain highly lucrative licensing revenues. The patents have brought the university between \$300 and \$400 million in licensing royalties over the past 2 decades.” *Id.*

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

50. Garde, *supra* note 12, at 246.

51. See Brief of Petitioner at 13, *Duke Univ. v. Madey*, 539 U.S. 958 (2003) (No. 02-1007).

52. *Duke Univ. v. Madey*, 539 U.S. 958 (2003).

53. The fact that certiorari was granted in *Integra* may affect this issue as well, but a general exemption for university research as a per se non-business research is (rightfully so, in light of the commercial nature) not warranted.

being said, Part II.C discusses the only defensive tools reasonably applicable to commercial use—those created by statute.

The German Federal Supreme Court took a similar stand<sup>54</sup> in its landmark opinion *Clinical Tests II (Klinische Versuche II)*.<sup>55</sup> It pointed to the impossibility of differentiating between purely academic and commercial research.<sup>56</sup> It also highlighted that, in practice, biotechnological research will mostly be carried out by commercial enterprises or universities because of high costs.<sup>57</sup> It concluded that the research efforts of the latter are also commonly driven by commercial interests.<sup>58</sup>

*C. Statutory Experimental Use Exemption: The Hatch-Waxman Act*

Yet another, and the most relevant, understanding of experimental use is the statutory *de minimis* infringement provision. On September 24, 1984, President Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984,<sup>59</sup> commonly referred to as the Hatch-Waxman Act.<sup>60</sup>

The Hatch-Waxman Act provides for an abbreviated approval process for generic forms of previously approved pioneer drug products whose patents have or will soon expire or are proven invalid. A pharmaceutical company seeking approval to market a generic product must complete an Abbreviated New Drug Application (“ANDA”). . . . The ANDA applicant may rely upon the pioneer company’s tests. It need only prove that the generic contains the same active ingredient as, and is bioequivalent to, the patented drug.<sup>61</sup>

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54. The outcome of that case was of course different, but for other reasons discussed in Part III.C.

55. Bundesgerichtshof [BGH] [Federal Court of Justice], Apr. 17, 1997, 1997 NJW 3092, [1998] R.P.C. 423 (F.R.G.).

56. *Id.* at 3095, [1998] R.P.C. at 433.

57. *Id.*, [1998] R.P.C. at 437.

58. *Id.*, [1998] R.P.C. at 437–38.

59. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984). For a detailed discussion of all aspects of this statute, see Wooster, *supra* note 26, at 487.

60. The commonly referred to name of the Act refers to its co-sponsors, Senator Orrin Hatch (R-UT) and Representative Henry Waxman (D-CA).

61. See *Zenith Labs., Inc. v. Abbott Labs.*, No. 98-1661, 1996 U.S. Dist. LEXIS 22567 at \*4 (D.N.J. Aug. 5, 1996).

The Act provided the first and only<sup>62</sup> specific research-use exemption in 35 U.S.C. § 271(e)(1), which provides as follows:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) *solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.*<sup>63</sup>

“Under a literal interpretation of patent law, it is clear that ‘research exemption’-type of activities are literal infringements . . . .”<sup>64</sup> Congress explicitly exempted certain infringing activities from the scope of the patent protection for policy considerations.

As Judge Nies observed in *Eli Lilly & Co. v. Medtronic, Inc.*,<sup>65</sup> “section 271(e)(1) was added to overrule this court’s decision in *Roche*.”<sup>66</sup> In *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*,<sup>67</sup> the Federal Circuit held that experimental use did not encompass the use of a patented compound for federally mandated pre-marketing tests even if the new drug (here, the one marketed by Bolar) would not enter the market prior to patent expiration.<sup>68</sup> The legislature agreed with the pharmaceutical company’s argument that patents will, under the *Roche* rule, be *de facto* extended if competitors must wait on mandatory bioequivalency tests until the patents expire.<sup>69</sup>

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62. “Only” refers to the “only one applicable in the context of patents.” *Id.* There is another statutory research exemption that deals with the use and reproduction of protected plant varieties. See 7 U.S.C. § 2544 (2000). Section 2544 provides that “[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act.” *Id.*

63. 35 U.S.C. § 271(e)(1) (2000) (emphasis added).

64. Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q. J. 52, 54 (1993).

65. 872 F.2d 402 (Fed. Cir. 1989), *aff’d*, 496 U.S. 661 (1990).

66. *Id.* at 406.

67. 733 F.2d 858 (Fed. Cir. 1984).

68. *Id.* at 860–61.

69. For a more detailed analysis of the underlying policy considerations, see Bruzzone, *supra* note 64, at 54.

*D. Scope of Experimental Use Provision*

In the United States, courts have generally conceded that the use of a patented invention solely to develop generic drugs for purposes of FDA approval does not constitute infringement.<sup>70</sup> However, this very broad statement does not help in comparing U.S. and German provisions; instead, it compels a closer look at the statutory language.

Both legislative concepts provide a safe harbor from infringement if the experiment “relates” (or “reasonably relates” under U.S. law) to admission of a compound under U.S. law or the patented subject matter itself under German law. Needless to say, this “relationship” is open to interpretation as to when infringement is considered “reasonable.”

The most commonly applied test is whether a reasonable defendant would have believed that there was “a decent prospect that the use in question would contribute to the generation of the kind of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product.”<sup>71</sup> That does not, however, answer the question, because it is unclear what information a party may believe to be relevant and what information it may not believe to be relevant.

The U.S. District Court for the Northern District of California took a very narrow approach in *Scripps Clinic & Research Foundation v. Gentech, Inc.*,<sup>72</sup> holding that experimental use was limited to bioequivalency tests for FDA approval and, thus, did *not*, as the defendant asserted, cover all uses “reasonably related to FDA testing,” but only use solely related to obtaining data for bioequivalency testing mandated by FDA rules.<sup>73</sup>

This approach finds support among some scholars:

On its face, the [U.S.] exemption appears to be very broad, applying to a wide range of potential infringers and activities. The legislative history, however, indicates that Congress was concerned with a very narrow class of infringers and range of activities. Specifically, the legislative history indicates that the

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70. See, e.g., *Schering Corp. v. Geneva Pharm., Inc.*, 275 F. Supp. 2d 534 (D.N.J. 2002), *aff'd on other grounds*, 339 F.3d 1373 (Fed. Cir. 2003).

71. See *Wooster*, *supra* note 26, at 525 (citing *In re '639 Patent Litigation*, 154 F. Supp. 2d 157 (D. Mass. 2001)).

72. 666 F. Supp. 1379 (N.D. Cal. 1987).

73. *Id.* at 1396.

exception was only meant to protect bioequivalency testing by generic manufacturers.<sup>74</sup>

One can well argue whether this holding went beyond the intention of Congress, because the statute explicitly states that the exemption shall apply to “solely all uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”<sup>75</sup> That was exactly what the defendant asked the court to hold.

This viewpoint, in the eyes of the author, cannot be rebutted merely by asserting the legislative intent and invoking the general principle that experimental use be construed “very narrowly.”<sup>76</sup> As the U.S. Supreme Court held, “[i]t is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.”<sup>77</sup> Congressional intent, thus, does not necessarily limit a statute to its language.

A limitation to bioequivalency testing for FDA approval does seem unwarranted by law. Congress would have chosen a different wording if it meant to narrow the statute in this way. The wording of § 271(e)(1), especially by stressing “all uses” and “development and submission,” suggests that the Northern District of California somehow went beyond Congress’ intent. As the U.S. Supreme Court established, courts cannot generally override the statutory wording if it is clear: “[A judge’s] inquiry must cease if . . . ‘the statutory scheme is coherent and consistent.’”<sup>78</sup> However, that might not exactly be the case. The statute is, in the words of Judge Nies, “fraught with ambiguity.”<sup>79</sup> That question does not need to be pursued in depth though, because the Northern District of California reverted to the more commonly used standards in *Intermedics*, stating that the applicable test was whether the defendant could reasonably believe in a “decent prospect” of its conduct to generate information relevant for FDA approval.<sup>80</sup> In the same opinion,

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74. William S. Feiler & Paula K. Wittmayer, *Protecting Research to Develop Drugs*, 229 N.Y. L.J. 9 (2003).

75. 35 U.S.C. § 271(e)(1) (2000).

76. See *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (citing *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

77. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 n.2 (1990) (quoting *Pittston Coal Group v. Sebben*, 488 U.S. 105, 115 (1988)).

78. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (quoting *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 240 (1989)).

79. *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405 (Fed. Cir. 1989), *aff’d*, 496 U.S. 661 (1990).

80. See *Intermedics v. Ventritex, Co.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).

the court held that the experimental use exemption also applied to medical devices.<sup>81</sup>

The Federal Circuit's latest statements on experimental use are to be found in the recently vacated *Integra* opinion.<sup>82</sup> *Integra* held a patent for a certain polypeptide sequence; Merck used this compound for research purposes.<sup>83</sup> Merck asserted § 271(e)(1) as a defense because it was using the drug to search for new drugs that would be subject to FDA approval.<sup>84</sup> The Federal Circuit held that Merck was not eligible for the § 271(e)(1) defense because "general biomedical research aimed towards identifying new compounds"<sup>85</sup> was not what Congress warranted by creating a safe harbor for generic drugs. In the words of Judge Rader, "§ 271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an [sic] FDA approval process."<sup>86</sup>

Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not reasonably related to the development and submission of information to the FDA.<sup>87</sup>

However, the court voted for a broader understanding of the Hatch-Waxman Act: "It does not follow from this, however, that the § 271(e)(1)'s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA."<sup>88</sup> Thus, it did not only come out on the side of Merck but also sided with the U.S. government. The acting Solicitor General, along with several other government leaders, filed an amicus curiae brief on behalf of the United States<sup>89</sup> expressing discomfort with the holding of the Federal Circuit and arguing that the decision "will likely hinder the development of important and medically

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81. *Id.* at 1272.

82. *Merck KGAA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 *passim* (2005).

83. *Id.* at 2377-78.

84. *Id.* at 2378-79.

85. *Integra Lifesciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 866 (Fed. Cir. 2003).

86. *Id.* at 867.

87. *Merck KGAA*, 125 S. Ct. at 2382 (internal quotation marks omitted).

88. *Id.*

89. Brief for the United States as Amici Curiae Supporting Petitioner at 20, *Merck KGAA v. Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237).

valuable new drugs.”<sup>90</sup> Section 271(e)(1), as construed by the U.S. Supreme Court, leaves “simply no room . . . for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.”<sup>91</sup>

The U.S. Supreme Court’s construction of § 271(e)(1) is, as the following explanations will show, closer to the German understanding than the Federal Circuit’s opinion.

### III. EXPERIMENTAL USE IN GERMAN PATENT LAW

German patent law provides for general protection of the patent/patentee in a similar way the protection works in U.S. law; however, as a civil law country, these protections are provided solely through statutes.<sup>92</sup> Sections 9 and 10 of the German Patent Act (PatG) are entitled “Effect of the Patent” (“Wirkung des Patents”).<sup>93</sup> Section 9 prohibits direct use by third parties and § 10 prohibits indirect use by third parties.<sup>94</sup> Similar to U.S. patent law, third parties are not only restricted from using the patented product, but are also restricted from producing, offering for sale, or placing into commerce a product that falls within the scope of the patented subject matter.<sup>95</sup> Exemptions are now set out in § 11, which is expressly entitled “Restrictions of the Effect of the Patent” (“Beschränkung der Wirkung des Patents”).<sup>96</sup>

#### A. The 1968 Patent Act

Before experimental use was explicitly covered in the 1981 PatG, § 6 of the statutory predecessor, the 1968 PatG,<sup>97</sup> contained a rather ambiguous wording construed by most authorities in a way to allow experimental conduct as long as the experiment constituted *an action in*

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90. Carney, *supra* note 45, at 2.

91. *Merck KGAA*, 125 S. Ct. at 2380.

92. For the sake of consistency, the symbol “§” is used for both U.S. and German codifications although—widely unknown even among scholars—it does not mean “section,” but “paragraph” throughout Europe. However, in Europe, a paragraph is not the sub-element of a section, but vice versa; thus, using the sign as opposed to the more commonly pursued approach of omitting the sign in international documents and using the word “section” is preferable. Accordingly, “§ 9 PatG” would be referred to by any European lawyer as “paragraph 9,” but has the meaning of “section 9” in the U.S. law context.

93. Patentgesetz [Patent Act], Dec. 18, 1980, BGBl. I, §§ 9, 10 (F.R.G.).

94. *Id.*

95. *See id.*

96. *Id.* § 11.

97. Patentgesetz [Patent Act], Jan. 2, 1968, BGBl. I, § 6 (F.R.G.).

*the private sphere without further commercial motivation.*<sup>98</sup> This did not allow economic use of the invention, but restricted tests to acts of private use, that is, verification that the patented invention was working properly and pure laboratory testing.<sup>99</sup>

The German Federal Court of Justice (Bundesgerichtshof) held in *Ethofumesat*<sup>100</sup> that third party use constituted an infringement when the third parties used an herbicide product containing the patented active substance in field tests during the term of the patent to explore whether the substance was effective, not injurious to human health, and environmentally friendly.<sup>101</sup>

According to the German Federal Court's construction of the 1968 PatG, which still applied to that particular case, such experiments were exempt if the sole purpose was to improve the invention. Because the experiments in question served to obtain data necessary to ensure compliance with the Federal Agency for Drugs and Pharmaceuticals (BfA Pharm)<sup>102</sup> approval procedure and not to improve the invention, this conduct was not covered by the experimental use exemption. A leading commentary on the PatG stated that only scientific experiments were admissible<sup>103</sup>—an opinion not upheld in later editions after the modification of the 1981 PatG.<sup>104</sup>

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98. “[E]ine Handlung im privaten Bereich ohne weitergehende ‘gewerbliche Zwecke.’” Peter Chroziel, *Zulassungshandlungen mit patentierten Arzneimittelerfindungen durch Zweitanmelder in der Bundesrepublik Deutschland und den USA* [Admission Activities with Patented Drug Inventions by Second Applicants in the Federal Republic of Germany and in the U.S.], 1984 GRUR INT. 735, 738.

99. See Ingeve B. Stjerna, *Die Voraussetzungen und Grenzen des patentrechtlichen Versuchsprivilegs* [Preconditions and Borders of the Experimental Use Exemption in Patent Law], 2004 GRUR 343, 344 (referencing applicable case law); Thomas Hieber, *Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 PatG* [Admissibility of Experiments with Patented Inventions Pursuant to § 11(2) of the Patent Act], 1996 GRUR 439, 440.

100. Bundesgerichtshof [German Federal Supreme Court], Feb. 18, 1992, 107 Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] 46 (F.R.G.), 1990 GRUR 997.

101. *Id.*

102. Federal Agency for Drugs and Pharmaceuticals (Bundesanstalt für Arzneimittel und Pharmaprodukte) is the German equivalent of the United States' Food and Drug Administration (but only supervising medicinal products). There is also the Federal Health Agency (Bundesgesundheitsamt) with its own expertise.

103. Georg Benkard, Annotation, *Patentgesetz und Gebrauchsmustergesetz* [Patent Act and Design Patent Act], Patentgesetz [Patent Act], Dec. 18, 1980, BGBl. I, §§ 9, 10 (F.R.G.) (as amended by Law of Dec. 20, 1991) (argument upheld until 7th ed.).

104. See Georg Benkard, Annotation, *Patentgesetz und Gebrauchsmustergesetz* [Patent Act and Design Patent Act], Patentgesetz [Patent Act], Dec. 18, 1980, BGBl. I, §§ 9, 10 (F.R.G.) (as amended by Law of Mar. 23, 1993) (argument upheld until 9th ed.).

### B. The 1981 Patent Act

The reason for including an explicit experimental use exemption in the PatG was that compliance with European Union harmonization efforts had to be reached. Section 11(2) of the 1981 PatG is derived from the ratification of the Convention for the European Patent for the Common Market (Gemeinschaftspatentübereinkommen) (CPC).<sup>105</sup> Article 31(b) exempts from liability for patent infringement all “acts done for experimental purposes relating to the subject-matter of the patented invention.”<sup>106</sup> This provision was introduced almost verbatim into most European national laws.<sup>107</sup> “Of the original signatories of the Community Patent Convention, The Federal Republic of Germany, France, the United Kingdom, Belgium, Spain, and Denmark have amended their patent laws to essentially copy the provisions of the Act.”<sup>108</sup>

In Germany, the CPC rules became part of the 1981 PatG.<sup>109</sup> As amended in 1981, they now provide that the effect of a patent should not reach “acts for experimental purposes that relate to the subject matter of the patented invention.”<sup>110</sup> It should be noted that the present PatG will soon be amended again, mainly because of Germany’s obligation to implement the EC Biotechnology Directive into national law. The draft of the Act for the Introduction of the Directive on the Legal Protection of Biotechnological Inventions<sup>111</sup> does not, however, provide for any alterations of the existing experimental use exemption; thus, the present wording will remain unchanged.

### C. Scope of Experimental Use Provision

The scope of § 11(2) of the PatG had been subject to discussion among lower courts and scholars alike. The Landgericht Berlin, as

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105. Convention for the European Patent for the Common Market, Dec. 15, 1975, BGBl. II, 833 (F.R.G.), 15 I.L.M. 5 (1976) [hereinafter CPC].

106. *Id.* at art. 31(b) (renumbered as art. 27(b) in Dec. 15, 1989 amendment).

107. Especially the Netherlands form an exception here, as the pertinent wording of the Dutch Patent Law 1995, Article 53(3) reads as follows: “The exclusive right shall not extend to acts solely serving for research on the patented subject-matter, including the product obtained directly as a result of using the patented process.” See Cornish, *supra* note 11, at 736.

108. See Bruzzone, *supra* note 64, at 62 (footnotes omitted).

109. Patentgesetz [Patent Act], Dec. 18, 1980, BGBl. I, §§ 11(2) (F.R.G.)

110. This is a translation of the German wording, which reads as follows: “Die Wirkung des Patents erstreckt sich nicht auf Handlungen zu Versuchszwecken, die sich auf den Gegenstand der patentierten Erfindung beziehen.”

111. BTDrucks 14/5642.

court of first instance,<sup>112</sup> argued that § 11(2) is simply to be seen as a codification of case law regarding the 1968 version of § 6;<sup>113</sup> thus, the principles stated under Part III.A. apply. However, the Federal Supreme Court has taken a much more liberal approach in two landmark decisions.

#### 1. Federal Supreme Court, *Clinical Trials I*

In *Clinical Trials I*,<sup>114</sup> the plaintiff was the exclusive licensee of a patent that covered human immune interferon, the so-called interferon gamma.<sup>115</sup> One of the defendants imported the active ingredient and used it to produce “Polyferon,” a pharmaceutical approved by the Federal Public Health Department for the treatment of chronic polyarthritis, the classic rheumatoid arthritis.<sup>116</sup> He sold it to another defendant who distributed the “Polyferon.”<sup>117</sup> The defendants were conducting clinical studies with the patented substance with a view to identify additional, conceivable indications.<sup>118</sup>

The Federal Supreme Court, in the words of Supreme Court Judge Professor Dr. Meier-Beck, “rejected a recourse to the decisions made under the Patent Act of 1968, including the ‘*Ethofumesat*’-decision . . . . [Its] main considerations were the following: [§ 11(2)] had no corresponding provision in the previous statutes, and the provision was adopted almost verbatim from the Community Patent Convention.”<sup>119</sup>

According to Judge Meier-Beck, this shows that the “German legislative body [did not simply want] to codify existing national law and jurisdiction.”<sup>120</sup>

Therewith—as the Bundesgerichtshof [Federal Court of Justice] says—the exempted tests were not defined positively but

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112. Under German civil procedure rules, a Landgericht is court of first instance in all civil actions exceeding 5000 Euro in value, and in special cases such as patent and trademark actions. In all civil actions not exceeding 5000 Euro in value, the Landgericht sits as a Court of Appeals.

113. *Klinischer Test* [*Clinical Test*], 1985 GRUR 375, 376 (LG Berlin).

114. Bundesgerichtshof [BGH] [Federal Court of Justice], July 11, 1995, 1996 GRUR 109, [1997] R.P.C. 623 (F.R.G.).

115. *Id.* at 109, [1997] R.P.C. at 629.

116. *Id.* at 110, [1997] R.P.C. at 630–31.

117. *Id.*

118. *Id.*

119. Peter Meier-Beck, *Clinical Trials and the Patent Law’s Test Privilege*, at 4, <http://www.italy.les-europe.org/docs/meier.pdf> (lasted visited Jan. 21, 2005) (emphasis added).

120. *Id.*

a negative delimitation was given: Any activities are excluded from test privilege which use an invention as the *means* for experimental acts; in such cases the invention is no longer used for purposes of experimentation.

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Accordingly, the wording of [§ 11(2)] of the Patent Act and the legislative speak for the assumption that clinical trials are exempted (enjoy the test privilege) even when the patented active substance is used with the objective of finding whether and, where appropriate, with what form of administration and dosage it is able to cure or alleviate certain human diseases. These trials are exempted as a matter of principle, regardless whether, beyond the pure research character of the trials, economic interests are also in the background, which can anyway hardly ever be ruled out.<sup>121</sup>

Judge Meier-Beck also expressed his view that the Federal Supreme Court's decision in *Clinical Trials I* is in accord with the decision of the British Court of Appeal in *Monsanto*.<sup>122</sup> "Therefor, [sic] the admissibility of clinical tests is [not] barred by the [fact] that these test[s] are typically carried out with the further objective of obtaining [regulatory] approval."<sup>123</sup>

This decision was affirmed<sup>124</sup> by the Federal Constitutional Court (Bundesverfassungsgericht), holding that the Federal Supreme Court's construction of § 11(2) did not violate the constitutional property guarantee set out in Article 14 of the German Constitution (Grundgesetz).<sup>125</sup>

## 2. Federal Supreme Court, *Clinical Trials II*

In *Clinical Tests II*,<sup>126</sup> the Federal Supreme Court was confronted with the following fact pattern: clinical trials were performed with a preparation containing recombinant human erythropoietin (EPO) to confirm results obtained in animal tests and to generate data required

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121. *Id.* at 4-5 (translation added).

122. [1985] R.P.C. 515, 1987 GRUR INT 108 (Eng.).

123. Meier-Beck, *supra* note 119, at 5.

124. Procedurally, what happened is called "nonacceptance of a constitutional complaint" ("Nichtan-nahme einer Verfassungsbeschwerde"), which is similar to the U.S. Supreme Court's denial of a writ of certiorari.

125. *See* Bundesverfassungsgericht [BVerfG] [Federal Constitutional Court], May 10, 2000, 1 BvR 1864/95, 2001 NJW 1783.

126. Bundesgerichtshof [BGH] [Federal Court of Justice], Apr. 17, 1997, 1997 NJW 3092, [1998] R.P.C. 423 (F.R.G.).

for regulatory approval.<sup>127</sup> It welcomed the occasion to confirm its holding in *Clinical Test I*:

As [§ 11(2) of the PatG] neither qualitatively nor quantitatively limits the experimental activities . . . . According wording of the law it is [not relevant whether the tests yield] scientifically or commercially usable results, or whether the test of a protected active agent achieves the aim of obtaining data of legal pharmaceutical permission . . . . [The only requirement is that the tests are intended to yield information related to the patented subject matter.] . . . This is also the situation if—as in the case in dispute—a pharmaceutical compound which contains the protected active agent should be tested in a clinical experiment with regards to its effectiveness and digestibility. [It is not evident from the wording of the provision that it would exclude an economical orientation or commercial objective of the experimental conduct.]<sup>128</sup>

The Federal Supreme Court did find, as it had not found in *Clinical Trials I*, that the trials conducted solely for obtaining regulatory approval do qualify for the experimental use exemption. “[T]he plaintiff is not successfully able to validate a differentiation between research activities which serve to develop further and improve an active agent protected by patent and such activities which have as their purpose the fulfilment of the regulations for authorisation.”<sup>129</sup>

One may think that this is self-evident, because the German provisions so far do extend beyond the scope of Hatch-Waxman Act. But, at least *prima facie*, ambiguous messages in that respect still seem to be sent by members of the Federal Supreme Court’s Tenth Senate. Judge Meier-Beck posed the following questions:

This may really be the decisive question: Were the trials, apart from other intentions, also aimed at exploring the unknown and bringing out new facts or solving remaining uncertainties? If yes, the test privilege is applicable. Or is demonstrating well-known facts to the competent authority the sole intention of the tests? If this is the case, the tests are not privileged trials in accordance with [§ 11(2)] of the 1981 Patent Act.<sup>130</sup>

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127. *Id.* at 3092, [1998] R.P.C. at 427–30.

128. *Id.* at 3096, [1998] R.P.C. at 433.

129. *Id.* at 3095, [1998] R.P.C. at 436 (citing Bundesgerichtshof [BGH] [Federal Court of Justice], July 11, 1995, 1996 GRUR 109, [1997] R.P.C. 623 (F.R.G.)).

130. Meier-Beck, *supra* note 119, at 9.

This view is shared by another prominent member of the Tenth Senate, Judge Alfred Keukenschrijver.<sup>131</sup>

The quotation above certainly raises questions as to the very idea of generic manufacturing, the questions to which Judge Meier-Beck provided a quite vague answer. “It is a question of fact which is the right one of these categories for tests necessary to obtain regulatory approval for a generic product. I do not dare to answer this, as I simply lack sufficient expert knowledge on this field of technology.”<sup>132</sup>

The aforementioned remarks are somewhat confusing and should be clarified. Whenever a generic producer aims to design around a patented product and uses the patented product to obtain regulatory approval, he shall be exempt from infringement under German (and U.S.) law. The Federal Supreme Court simply held that experiments are not subject to the experimental use safe harbor if they serve solely to verify business questions, such as whether there is a demand in the market or an acceptance of price ranges or distribution channels.<sup>133</sup>

The Federal Supreme Court certainly did not, and did not mean to, exclude tests for obtaining regulatory approval, which have to be seen as within the scope—if not at the heart—of § 11(2), even when they do not reveal new facts. This approach is visible in the Landgericht’s holding in *Clinical Trials II*.

The Landgericht, as a court of first instance, found that testing for the purposes of regulatory marketing approval was not within the scope of § 11(2), a point the Federal Supreme Court expressively dismissed as discussed earlier.

Moreover, in *Clinical Trials II*, the Federal Supreme Court stated an important difference between *Clinical Trials I* and *II*.

[In contrast to *Clinical Trials I*], it is here not a matter of the discovery of further indications, rather of facts concerning the characteristics of the active agent in accordance with the patent in the context of the well-known indications. These experiments are activities which are related to the object of the invention.<sup>134</sup>

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131. See Alfred Keukenschrijver, 2002 MITT. DT. PA. 2, 5 (2002).

132. Meier-Beck, *supra* note 119, at 9.

133. See Bundesgerichtshof [BGH] [Federal Court of Justice], Apr. 17, 1997, 1997 NJW 3092, 3094, [1998] R.P.C. 423, 433–34 (F.R.G.).

134. *Id.*, [1998] R.P.C. at 431.

#### IV. DEFINITION AND INTERPRETATION OF DIFFERENCES

##### *A. Differences in Statutory Wording*

Comparing the German and U.S. provisions, it becomes apparent that each provision is both broader and narrower than the respective other statute. In total, the U.S. provision contains the more detailed, and, thus, much more restrictive approach.

The German provision only allows experiments relating to the patented subject matter; the meaning of such a restriction will be discussed later. Hatch-Waxman Act provides, in pertinent part, for no such restriction, but requires experiments to reasonably relate to regulatory admissions under federal law, which can be simplified by the term “relating to FDA approval only.” This, of course, is a very severe restriction that excludes testing in any respect not related to FDA approval, leaving entire industrial branches with no need to obtain a “go ahead” from the FDA. That being said, the only situation in which the U.S. regulation would be broader than the German counterpart could be an experiment required by the FDA but *not* relating to the patented subject matter. Under a reasonable construction of the term “relate,” this is a rather theoretical case. The U.S. regulation further excludes new animal drugs and certain veterinary biological products, which are described very precisely in the statute.<sup>135</sup> The PatG contains *no* restriction regarding the eligible subject matter.

##### *B. Evaluation of Differences*

In Germany, the term “relate” enjoys a rather broad construction. Shortly after § 11(2) was introduced, the majority of scholars and practitioners read the statute in such a way that all experimental conduct with patented subject matter was permissible and the limitation “relating to the subject matter of the patented product” simply excluded experiments if the aim of the tests was to obtain information about marketability of the patented invention or in which the patented compound was used as an “apparatus” to test something different.<sup>136</sup>

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135. 35 U.S.C. § 271(e)(1) (2000).

136. See e.g., Peter Chrocziel, *Die Bneutzung patentierter Erfindungen zu Versuchs-und Forschungszwecken* [Use of Patented Inventions for Experimental and Research Purposes], 1986 GRUR 148, 195. See also Rudolf Teschemacher, *Biotechnologische Erfindungen in der Erteilungspraxis des Europäischen Patentamtes* [Biological Inventions in the Prosecution Practice of the European Patent Office], 1987 GRUR INT. 303, 303–10.

An example for the latter “apparatus” test would be to use a patented refrigerator in order to examine the effect of very low temperatures on certain (other) products. An experiment relating to the patented subject matter would be validly conducted when the refrigerator is used in the same way, but in a way to see how efficiently the refrigerator cools other products.<sup>137</sup>

In the opinion of the author, this very fine (or, in a less positive perception, artificial) delineation provokes misuse. As the above example shows, impermissible and permissible action are just two sides of the same process. On the other hand, those tests are not primarily about simply obtaining information (that is, how efficiently can the refrigerator cool my product). If the information is necessary for authorities, then secretly obtained data does not help. Because test results have to be submitted, the illegal conduct thereby will be disclosed, which devalues the incentive for circumvention.

Although one may sometimes overestimate the differences between civil and common law systems, courts are even less likely and less able to introduce additional bars or requirements when facing somewhat clear statutory language in civil law countries. That being said, the only limitations of experimental use in Germany are those which can be extracted from the wording of § 11(2). Because there is no such thing as an additional common law experimental use and the statute does not provide for a different treatment of commercially motivated experiments, there is no difference between commercial and noncommercial conduct under German patent law.

## V. CONCLUSION AND OUTLOOK

It has been frequently said that comparisons without evaluation are of limited value. A leading treatise on comparative law makes a valid point in stating that the “comparatist’s power and duty to make a critical evaluation [of the analysis, otherwise] comparative law can easily degenerate into a dizzying spiral in which everything is both cause and effect; different from, but similar to, anything else; separate but intertwined.”<sup>138</sup>

On the other hand, this should not lead the reader to believe that there is a “winner” to be declared whose system has to be copied by the “loser.” In the opinion of the author, the approach of a good

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137. See as an example Gottfried Freier, *Patentverletz-ung und Versuchsprivileg* [*Patent Infringement and Experimental Use Exemption*], 1987 GRUR 664, 666.

138. GLENDON ET AL., *supra* note 4, at 8.

comparison should be rather biblical—*literally* biblical if applying the word of St. Paul: “Probe everything and retain the best.”<sup>139</sup> So what is “the best”? What has to be retained? That, of course, depends on the aim that is pursued by the legislator. In the following discussion, the author will show that the U.S. and the German legislator, although *prima facie* developing solutions to the identical task of promoting “the Progress of Science and Useful Arts,”<sup>140</sup> were seeking to reach quite different objectives.

As evident from the discussion above, the experimental use defense is broader under German law than under U.S. law. There may be several reasons why the compromise has been struck differently in the United States than in Germany. The most apparent one is that the benefit to the public is weighed differently. As Judge Rader stated in the *Integra*, the Hatch-Waxman Act was “designed to benefit the makers of generic drugs, research-based pharmaceutical companies, *and not incidentally the public.*”<sup>141</sup> Although the government’s interest in low drug costs might well have played a role in the already discussed reversal of this opinion by the U.S. Supreme Court, this does not change the general approach. According to another opinion of the Federal Circuit, “Congress struck a balance between *two* competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”<sup>142</sup>

That being said, it is obvious that, under U.S. law, only *two* parties and their interests had to be reconciled, and public factors are considered as “secondary effects” only.<sup>143</sup> Whereas, in Germany, one can make the argument that the public interest *directly* weighs in on the side of the generic drug manufacturers.

Although there is no specific reference to the public good in the statute, numerous scholars have elaborated on the public good as a

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139. 1 *Thessalonians* 5:21.

140. U.S. CONST. art. I, § 8, cl. 8. The German legislative aim is equivalent, yet not codified on a constitutional level.

141. *Integra Lifesciences I, Ltd. v. Merck KGAA*, 331 F.3d 860, 865 (Fed. Cir. 2003) (quoting *Glaxo, Inc. v. Novapharm, Ltd.*, 110 F.3d 162, 1568 (Fed. Cir. 1997)) (emphasis added).

142. *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003) (quoting *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)) (emphasis added).

143. For a broader view on the role of public interest in patent cases with special focus on the biotechnology sector, see Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

factor to consider in construing the experimental use defense.<sup>144</sup> As Professor Straus pointed out,<sup>145</sup> the “legitimate interest of the public in information relevant for improving medical care depends upon the clinical testing.”<sup>146</sup> In this context, he described the interests of the public and the interest of the applicant for the new patent as being “in accord.”<sup>147</sup> It is evident that, in developing a compromise between interests, the acknowledgement of a public good factor weighing in on one side of the scale in German law left less room for the interests of the patentees than under the U.S. system.

As the course of research revealed, the most significant factor is a totally different approach of the legislature; Congress simply did not want to create a general experimental use defense. Section 271(e)(1) took a very specialized approach and simply aimed to overcome the problem created (or, to be fair, visualized) by the Federal Circuit in *Roche*. Scholars in this country have been criticizing this point of view and argued in favor of a general experimental use exception,<sup>148</sup> whereas others argue that “an exception allowing experimental use of another person’s invention should only be allowed if the overall social utility increases.”<sup>149</sup>

The German provision, on the other hand, explicitly represents a general experimental use defense, as it is also known in Japan and most European countries.<sup>150</sup> It covers experiments conducted with a commercial motivation, allows research for not only existing and new indications,<sup>151</sup> and does not restrict clinical trials for regulatory approval.

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144. See, e.g., Jochen Pagenberg, *Das Versuchsprivileg des § 11 Nr. 2 PatG [The Experimental Use Exemption in § 11(2) of the Patent Act]*, 1996 GRUR 736; Hieber, *supra* note 99, at 445; Joseph Straus, *Zur Zulaessigkeit klinischer Untersuchungen am Gegenstand abhaengiger Verbesserungserfindungen [To the Admissibility of Clinical Trials with Dependent Improvement Inventions]*, 1993 GRUR 308, 318.

145. Straus, *supra* note 144, at 318.

146. Professor Straus’ strong emphasis on public good has recently been criticized by Rolf Pietzcker, who argues for stronger patent protection and narrow construction of § 11(2). Rolf Pietzcker, *Patentrechtliche Fragen bei klinischen Untersuchungen—eine Erwiderung [Questions of Patent Law With Regard to Clinical Trials—A Rebuttal]*, 1994 GRUR 319. The details of that controversy are beyond the scope of this Article, as Dr. Pietzcker does not generally oppose the public good as a factor for balancing interests.

147. See Straus, *supra* note 144, at 318.

148. See Bruzzone, *supra* note 64, at 52.

149. See Walters, *supra* note 24, at 522.

150. For a discussion of foreign provisions, see Bruzzone, *supra* note 64, at 61–62.

151. See Martin Faehndrich & Winfried Tilmann, *Patentnutzende Bereitstellungshandlungen bei Versuchen [Supply Activities Using the Patented Invention in Experiments]*, 2001 GRUR 901.

Its only limitations are that no purely market-oriented research (distribution, marketing, pricing) is covered and that the patented invention must not be an apparatus for the invention, but the object of those.

So what, to refer back to St. Paul, is the “best” which is to be retained? Should scholars and practitioners pursue the broader concept (Germany) or stick to the narrower construction (U.S.)? And, in this context, will or should the U.S. Supreme Court, which granted certiorari in *Integra*, uphold the present, narrow rules established under Federal Circuit law? An indication for a liberalization of present law can be seen in the grant of certiorari as such. The fact that the government in its amicus brief decided to weigh in against the Federal Circuit is an even stronger sign that some parameters might be shifted.

In this context, it is also worthwhile remembering that amendments to the Hatch-Waxman Act’s experimental use exception have been suggested only a few years after the provision was signed into law. In 1988, the American Bar Association Patent, Trademark & Copyright Committee passed a resolution favoring “in principle an exemption from infringement for activities conducted solely for experimental or research purposes, not limited to pharmaceutical products.”<sup>152</sup>

In the same year, an act was introduced into the House of Representatives by then Representative Kastenmeier stating the following:

[I]t would appear desirable to codify a coherent set of principles to guide conduct in this area. Congress should . . . amend title 35 to provide that the use of a patented invention or process is not an act of infringement if done for the purpose of experimentation and research. This requirement should not apply only to biotechnology but . . . to all patented inventions.<sup>153</sup>

In the author’s view, the European provisions and the amendments advanced by the Committee and Representative Kastenmeier suggest that there are several good reasons for a broader (yet certainly not infinite) experimental use exception. Because dependent inventions cannot be “disconnected” from the prior patents in their commercial use

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152. Bruzzone, *supra* note 64, at 66 (paraphrasing *The A.B.A. Patent, Trademark & Copyright Comm. Rep. Resolution 101-4*, 1988 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. REP. 25).

153. *Id.* at 66–67 (quoting H.R. REP. NO. 100-888 (1998)).

and because earlier inventors will still be adequately compensated,<sup>154</sup> the policy considerations on which patent law is founded seem to suggest that a broader research exception will further the overall good.<sup>155</sup> The value of a comparison is to show that a broader exception, in Germany as in many countries in the world, actually works without patentees having to fear a near-Marxist system obligating them to surrender intellectual property rights for some vague society benefit. In fact, Representative Kastenmeier referred, *inter alia*, to a German source when suggesting his modifications.<sup>156</sup> Moreover, these comparisons reveal that “[t]he lack of a codified experimental use provision in the United States stands in sharp contrast to the rest of the world,”<sup>157</sup> which is, of course, not sufficient to say that the U.S. system is in need of improvement.

Of course, patent owner’s interests have to be safeguarded appropriately. Thus, the author would not subscribe to the idea of a “fair use” idea in patent law—that is, allowing infringement whenever it is somehow socially beneficial.<sup>158</sup>

This Article also should not lead to the conclusion that the Federal Circuit was absolutely incorrect in *Integra*. In fact, legislative history and the wording of the statute seem more likely to support a narrow construction. The U.S. Supreme Court has, as mentioned above, referred to the exemption as “clinical trials exemption” in *Eli Lilly*,<sup>159</sup> yet at the same time it emphasized that there is no limitation to clinical trials.<sup>160</sup> In light of the ambiguities, it should have been the domain of Congress to open up the scope of Hatch-Waxman Act and to precisely define the limits. Instead, it has been felt obligated to act without precisely defining the limits.

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154. The author acknowledges that this is a subjective term and appreciates the problem connected with it. One could thus make an argument against that as well, which would be equally subjective; however, this is a problem implicit in most judgment calls.

155. Again, this is a subjective term depending on what a society defines as overall good.

156. H.R. REP. NO. 100-888, at 51 (citing P. CHROCZIEL, DIE BENUTZIND PATENTIERERER ERFINDUNGEN ZU VERSUCHS—UND FORSCHUNGSZWECKKN 174 (1986)).

157. See Christina Weschler, *The Informal Experimental Use Exception: University Research After Madey v. Duke University*, 79 N.Y.U. L. REV. 1536, 1539 (2004).

158. This is advocated by Maureen O’Rourke in *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1201 (2000).

159. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (emphasis added).

160. See *Merck KGAA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380–84 (2005).

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The effects of the *Integra* decision, however, are not unwelcome in light of policy considerations and differing standards abroad. The U.S. Supreme Court may well have (deliberately or not) complied with what some scholars have long since demanded:

To prevent the export of research to countries more “friendly” to reverse engineering, to avoid a chilling of research by the current state of confusion, and to encourage trade through a harmonized worldwide patent system, it is in the interest of the United States to resolve the current confusion and enact a research exemption .

<sup>161</sup>  
. . .

Time will tell whether the U.S. Supreme Court promoted or chilled research by its latest opinion. Monitoring how courts and Congress will proceed in the field of experimental use after *Integra* will remain an interesting and rewarding task. Reverting to the beginning of this Article, there is a final argument to be made for the use of international comparative law. International comparisons can, especially in highly specialized fields of international business like patent law, contribute significantly by showing alternatives, evaluating strengths and weaknesses of domestic and foreign approaches, providing material to reconsider legislative targets, and, finally, even by furthering harmonization of legal systems.

There is already evidence of this harmonization within the European Union in Article 10(6) of Directive 2004/27,<sup>162</sup> in which the European Union enacted a new provision commonly referred to as the “Roche-Bolar clause.” The provision reads as follows:

Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3, and 4 [i.e. the abbreviated procedure for obtaining market approval for generic medicinal products] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.<sup>163</sup>

The German legislature has already reacted and added § 11(2)(b) to the PatG, which is slightly different as it does not imply the requirement of an abridged procedure, but generally allows experimental use

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161. Bruzzone, *supra* note 64, at 69.

162. See Council Directive 2004/27, 2004 O.J. (L136) (EC) (amending Council Directive 2001/83, 2001 O.J. (L 311) (EC)).

163. *Id.*

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activities for obtaining market approval.<sup>164</sup> This is in line with the Federal Supreme Court's decision in *Clinical Trials II*.

The Federal Supreme Court decision and the Roche-Bolar clause thus “work together” to narrow the “transatlantic gap” between U.S. and German patent law, however positive or negative one might judge this to be.<sup>165</sup>

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164. Frank-Erich Hufnagel & Peter Ruess, *Neues zum Versuchsprivileg im US-Patentrecht—Gedanken zur Entscheidung des US Supreme Court in Merck v. Integra*, [News on Experimental Use in U.S. Patent Law—Thoughts on the U.S. Supreme Court Opinion in *Merck v. Integra*], 2005 MITT. DT. PA. 497, 502 (2005).

165. *Id.*

## APPENDIX: OVERVIEW CHART

	U.S. Patent Law 35 U.S.C. § 271(e)(1) (2000).	German Patent Law Patentgesetz, Dec. 18, 1980, BGBl. (F.R.G.).
Statutory Wording	It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.	Die Wirkung des Patents erstreckt sich nicht auf Handlungen zu Versuchszwecken, die sich auf den Gegenstand der patentierten Erfindung beziehen.  [The effect of the patent does not reach out to acts for experimental purposes which relate to the subject matter of the patented invention.]
Subject Matter Covered	All, except new animal drugs certain veterinary biological products  But, restrictions implied due to nature of experiment	All
Nature of Experiment (emphasis added)	<i>Solely</i> for uses <i>reasonably related</i> <i>to Federal regulatory approval</i>	<i>Solely</i> for purposes <i>related</i> <i>to subject matter of</i> <i>invention</i>