



# MAPPING THE CONTOURS OF THE EXPERIMENTAL USE EXEMPTION: 35 U.S.C. sect. 271(E)(1)'S PAST, PRESENT, AND FUTURE

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Mapping the contours of The Experimental Use exemption:

## 35 U.S.C. § 271(e)(1)'s Past, Present, and Future

A patent is a device to prevent the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse.... Since it is rooted in contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in particular instances, impeding progress unnecessarily even if its general effect is favorable on balance.<sup>1</sup>

*“If without fear of liability a competitor can assemble a patented item past the point of testing, [then] the... patent becomes worthless.”<sup>2</sup>*

## I. Introduction

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (DPCPTR).<sup>3</sup>This Act, which resulted from the lobbying efforts of both

<sup>1</sup>Joan Robinson, *The Accumulation of Capital* 87 (1956).

<sup>2</sup>*Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 19 (Fed. Cir. 1984).

<sup>3</sup>Pub. L. No. 98-417, Title II, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.). This Act is also known as the “Hatch-Waxman Act,” for its two original sponsors, Senator Orrin Hatch (R-Utah) and Representative Henry Waxman (D-California).

the pharmaceutical industry and consumer interest groups,<sup>4</sup> was intended to encourage greater expenditure in the area of pharmaceutical invention while simultaneously ensuring greater competition immediately after the expiration of the relevant patents.<sup>5</sup> “By rectifying distortions in the patent system created by the Food and Drug Administration’s [FDA’s] regulatory approval process, Congress struck a balance between the interests of pharmaceutical companies,... competing ‘generic’ manufacturers,” and consumers.<sup>6</sup>The Drug Price Competition and Patent Term Restoration Act created several modifications to conventional patent law, including:

· Provisions allowing for the extension of the normal term of a patent for up to five years to compensate a patent owner for the marketing time allegedly lost in satisfying government regulations requiring proof that a drug is safe and effective before it can be marketed.<sup>7</sup>

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<sup>4</sup>See H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 16–18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2686; William T. Christiansen, *Patent Term Extension of Pharmaceuticals in Japan: So you Say You Want to Rush That Generic Drug to Market in Japan.... Good Luck!*, 6 PAC. RIM L. & POL’Y J. 613, 616 (1997) (outlining the history of the Drug Price Competition and Patent Term Restoration Act of 1984).

<sup>5</sup>See Samuel M. Kais, *A Survey of 35 U.S.C. § 271(e)(1) as Interpreted by the Courts: The Infringement Exemption Created by the 1984 Patent Term Restoration Act*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 575, 576 (1997); Amy Stark, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 SAN DIEGO L. REV. 1057, 1059 (1994).

<sup>6</sup>Kais, *supra* note 5, at 576. Referring to the Drug Price Competition and Patent Term Restoration Act, Senator Orrin Hatch observed that the statute “represented a finely tuned balance which reflected the dynamics of the healthcare marketplace.” Reginald Rhein, *BIO, PhRMA Call For Longer Patent Lives to Make Up for FDA Review Lags*, BIOTECH. NEWSWATCH, Mar. 18, 1996, *available in* 1996 WL 8452664 (quoting Sen. Hatch). Senator Hatch also noted that “on the one end was the need of the innovator drug companies to rely on adequate intellectual property protection to ensure that they attract sufficient capital for research and development [while] on the other end were the fledgling generic drug companies, who were not able to bring their products to market quickly because of the FDA approval process and the patent law.” *Id.*

<sup>7</sup>Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA: J.L. & TECH. 389, 390 (1999) (citing 35 U.S.C. § 156 (1994)).

Special procedures for challenging the validity or infringement of drug patents which, in effect, guaranteed the patent owner a statutory preliminary injunction for a period of thirty months unless the adjudication was completed in a shorter time.<sup>8</sup> A “bounty” for challenging patent validity, infringement or enforceability in the form of 180 days of market exclusivity to the first generic applicant to file a patent challenge against any approved drug.<sup>9</sup> A novel statutory exemption from claims of patent infringement for those acts of making, using, or selling a patented invention which are reasonably related to seeking FDA approval to market a drug, provided that no commercial use of a patented invention occurs before the patent expires.<sup>10</sup>

This essay reviews this final provision, § 271(e)(1), which established that the use of an invention does not constitute patent infringement if that use is “reasonably related” to obtaining federal approval to market pharmaceutical or veterinary products.<sup>11</sup> Section 271(e)(1) creates a “safe harbor”<sup>12</sup> that reads:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (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>13</sup>

This essay examines the history and legislative intent behind § 271(e)(1)’s

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<sup>8</sup>*Id.* (citing 21 U.S.C. § 355(c) (1994) and 35 U.S.C. § 271(e)(2)–(4) (1994)). Collectively, these provisions are referred to as the “patent certification procedures of the Act. *See id.* at 391 n.6.

<sup>9</sup>*Id.* at 391 (citing 21 U.S.C. § 355(j)(5)(B)(iv) (1994)).

<sup>10</sup>*Id.* at 390 (citing 35 U.S.C. § 271(e)(1) (1994)).

<sup>11</sup>*See* Brian D. Coggio & Francis D. Cerrito, *The Application of the Patent Laws to the Drug Approval Process*, 52 FOOD & DRUG L.J. 345, 345 (1997).

<sup>12</sup>*See, e.g.*, Courtenay C. Brinckerhoff, *Can the Safe Harbor of 35 U.S.C. § 271(e)(1) Shelter Pioneer Drug Manufacturers?*, 53 FOOD & DRUG L.J. 643 (1998); Coggio & Cerrito, *supra* note 11, at 345–47.

<sup>13</sup>35 U.S.C. § 271(e)(1).

enactment, the statute's subsequent interpretation by the courts, and the role that the provision may play in the future in order to illustrate the inherent tensions between the FDA's drug approval process and the patent law and to highlight the difficulty of balancing the needs of consumers, pharmaceutical innovators, and generic drug companies.

## **II. The Origins of the Experimental Use Doctrine — Creation and Early Development**

### *A. Whittemore v. Cutter and Its Progeny*

Over 150 years before the patent law was amended to include § 271(e)(1), seeds for the statute’s enactment were sown in *Whittemore v. Cutter*,<sup>14</sup> in an opinion written by Justice Story while sitting on the Massachusetts Circuit Court.<sup>15</sup> In *Whittemore*, the defendant challenged the lower court’s jury instruction “that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right.”<sup>16</sup> Justice Story approved of the instruction, stating that “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce the described effects.”<sup>17</sup>

That same year, in *Sawin v. Guild*,<sup>18</sup> Justice Story again referred to this exemption from the patent law for experimental use. In holding that the defendant’s sale of a patented machine for cutting brad nails constituted patent infringement, Justice Story observed that the machine had been sold “with an intent to use for profit” rather than “for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.”<sup>19</sup> In order for there to be infringement, Justice Story asserted, “the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.”<sup>20</sup>

In both *Whittemore* and *Sawin*, Justice Story’s references to an exemption from the patent law for experimental use were dicta, and as a result, the early course of the exception was far from clear. Very few early courts applied the experimental use doctrine to excuse the use of a patented invention that would otherwise constitute infringement.<sup>21</sup> Nevertheless, most commentators agree that the common law of patents provides for an exemption from infringement for experimental use to ascertain the validity and exact specifications of a patent, in order to enable an individual to challenge a patent on the grounds of non-enablement or inutility.<sup>22</sup>

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<sup>14</sup>29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>15</sup>See Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 *High Tech. L.J.* 369, 371 (1992).

<sup>16</sup>*Whittemore*, 29 F. Cas. at 1121.

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

<sup>18</sup>21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

<sup>19</sup>*Id.* at 555 (internal citation omitted).

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

<sup>21</sup>See Michel, *supra* note 15, at 372; see also Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 *J. Pat. & Trademark Off. Soc’y* 617 (1985) (outlining the history of the experimental use exception from its creation to the Federal Circuit’s opinion in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*). Despite the skepticism with which courts greeted the doctrine, however, by 1861, the law was “well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the of the rights of the patentee.” *Peppenhause v. Falke*, 19 *Fed. Cas.* 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

<sup>22</sup>See, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and*

The scope of Justice Story’s “philosophical experimentation” exception has been more difficult for courts and commentators to define, however, because of the inherent ambiguity of that phrase.<sup>23</sup> Early courts seeking to apply this prong of Justice Story’s exception typically focused on the *experimental* nature of the conduct, without elaborating upon the meaning of “*philosophical* experimentation.”<sup>24</sup> Thus, other than establishing that commercial use and commercial

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Experimental Use, 56 U. Chi. L. Rev. 1017, 1074 (1989) (“The case of an experimental use exemption is strongest when the subsequent researcher is using a patented invention to check the validity of the patent holder’s claims. Free access to patented inventions for the limited purpose of permitting scrutiny of new research claims serves the policies underlying the patent law as well as the interests of research science. Indeed, patent law promotes scrutiny of the research claims embodied in patented inventions through its requirement that patent holders make enabling disclosures of their inventions freely available to the public.”); Michel, *supra* note 15, at 372 (“[T]he second prong of Justice Story’s test which allows activity for ‘ascertaining the verity and exactness of the specification’ does appear to be ‘well-settled.’”). The experimental use exception appears to have become fixed in American patent jurisprudence when Professor Robinson summarized the exception and included the doctrine in his treatise on patents. See W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890): § 898. No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention. [T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer’s knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimenter, or if the experiments are conducted with a view to the adaptation of the invention to the experimenter’s business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress. *Id.* (internal citations omitted).

<sup>23</sup> See, e.g., Michel, *supra* note 15, at 372 (noting that the scope of the philosophical experimentation prong is less clear than the “ascertaining the verity and exactness of the specification” prong).

<sup>24</sup> See, e.g., Ned A. Israelsen, *Making, Using, Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM. INTEL. PROP. L. ASS’N Q.J. 457, 460 n.11 & n.14 (1989); Michel, *supra* note 15, at 372.

intent forestalled application of the exception, these cases did little to establish its contours.<sup>25</sup>

In more recent years, however, the exception for philosophical experimentation has been both more clearly defined and more narrowly construed. In *Pitcairn v. United States*,<sup>26</sup> the Court of Claims refused to apply the experimental use exception because there was a business purpose underlying the infringing action.<sup>27</sup> The court concluded that the experimental use exception was not available as a defense to infringement because the nature of the tests, demonstrations, and experiments conducted, which included testing a helicopter for lifting ability, flight speed, range, and numerous other factors, were within the legitimate business of the defendant.<sup>28</sup> Thus, patented products that were not built *solely* for experimental use, although *primarily* used for testing and experimental purposes, were excluded from the experimental use exception.<sup>29</sup> According to the reasoning of the *Pitcairn* court, for an experimental use to be non-infringing under Justice Story's test, the use must be strictly for amusement, for satisfying idle curiosity, or for philosophical inquiry.<sup>30</sup> A second modern case to address

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<sup>25</sup> See Michel, *supra* note 15, at 372.

<sup>26</sup> 547 F.2d 1106 (Ct. Cl. 1976).

<sup>27</sup> See *id.* at 1125–26 (holding that the government's experimental use of patented products in helicopters was infringing because the tests had a legitimate business purpose).

<sup>28</sup> See *id.*

<sup>29</sup> See *id.* at 1124–26.

<sup>30</sup> See Todd A. Rathe, *Patent Law — Medical Device Experimental Use Exception in Patent Infringement: Eli Lilly v. Medtronic*, 16 J. CORP. L. 625, 631 (1991) (internal citations omitted).



the scope of Justice Story’s philosophical experimentation prong was *Pfizer, Inc. v. International Rectifier Corp.*<sup>31</sup>In this case, the federal district court for the Central District of California held that International Rectifier’s manufacture and use of doxycycline, a pharmaceutical compound patented by Pfizer, for bioequivalency and serum level tests, infringed Pfizer’s patent.<sup>32</sup>Although International Rectifier claimed that these tests were both solely experimental and necessary in order to obtain approval of its generic drug from the FDA, the court interpreted the history of the experimental use doctrine as suggesting that “the underlying rule of permissible experimental use demands that there must be no intended commercial use of the patented article, none whatsoever, if the exception is to be recognized at all.”<sup>33</sup>Thus, because International Rectifier intended to place its generic drug would in direct commercial competition with Pfizer’s doxycycline after the expiration of Pfizer’s patent, the court held that the experimental use exception was inapplicable.<sup>34</sup>

*B. The Federal Circuit’s Decision — Roche Products, Inc. v. Bolar  
Pharmaceutical Co.*

In 1984, the then newly created Court of Appeals for the Federal Circuit first considered the scope of the experimental use doctrine in *Roche Products,*

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<sup>31</sup>217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982).

<sup>32</sup>*See id.* at 158–59.

<sup>33</sup>*Id.* at 161.

<sup>34</sup>*See id.* at 163.

*Inc. v. Bolar Pharmaceutical Co.*<sup>35</sup>This case arose out of a dispute between Roche Products, Inc., a large research-oriented pharmaceutical company, and Bolar Pharmaceutical Co., a manufacturer of generic drugs. In early 1983, Bolar began investigating the possibility of marketing a generic drug equivalent to Roche's patented sleeping drug, Dalmane, after the expiration of Roche's patent.<sup>36</sup>Bolar immediately began working to obtain federal approval to market its generic equivalent of Dalmane. Bolar did not want to wait for Roche's patent to expire before taking steps to achieve FDA approval of its equivalent drug "[b]ecause a generic drug's commercial success is related to how quickly it is brought on the market, after a patent expires[,] [a]nd because approval for an equivalent of an established drug can take more than two years."<sup>37</sup>In mid-1983, Bolar began to perform tests on the active ingredient claimed in Roche's patent in order to obtain stability data and dissolution rates and to perform the bioequivalency and blood serum studies necessary for a New Drug Application (NDA) to the Food and Drug Administration.<sup>38</sup>

Upon learning of Bolar's actions, Roche filed a complaint in the United States District Court for the District of New Jersey seeking to enjoin Bolar from taking, during the life of Roche's patent, the statutory and regulatory steps necessary

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<sup>35</sup>733 F.2d 858 (Fed. Cir. 1984).

<sup>36</sup>*See id.* at 860.

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

<sup>38</sup>*See id.* The active ingredient claimed in Roche's patent was flurazepam hydrochloride (flurazepam hcl).

to market a generic version of Dalmane after its patent expired.<sup>39</sup> Bolar was subsequently granted a change of venue and the case was transferred to the federal district court for the Eastern District of New York.<sup>40</sup> After reviewing the case law and recognizing the limitation that the experimental use doctrine places on the patent right, the court held that Bolar's generic drug testing was an experimental use.<sup>41</sup> The court concluded that although Bolar's experimentation could not "be classified as merely for amusement or philosophical gratification[,] [a]t the same time, it [could] not be connected with any act of competition or profit during the term of the patent in either domestic or foreign markets. Its experimentation is commercial preparation of a non-production nature for post-expiration competition."<sup>42</sup> Because Bolar realized no benefit during the term of Roche's patent and because Bolar's activities did not reduce Roche's profits during the patent's term, the district court concluded that Bolar's use of the patented compound for federally mandated testing did not infringe Roche's patent.<sup>43</sup>

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<sup>39</sup> *See id.*

<sup>40</sup> *See id.*

<sup>41</sup> *See Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 572 F. Supp. 255, 257 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

<sup>42</sup> *Id.*

<sup>43</sup> *See id.* at 258 ("[T]he court cannot find a basis for holding that Bolar's limited experimental use of [the patented drug] would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent term."); *see also Roche*, 733 F.2d at 861 (noting that the lower court held that Bolar's use was de minimus and experimental); Rathe, *supra* note 30, at 631.

On appeal, the Federal Circuit reversed the district court's holding that Bolar did not infringe Roche's patent, stating that:<sup>44</sup>

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last six months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The district court held that it does not. This was an error of law.<sup>45</sup>

The court began by observing that it is well-established that the use of a patented invention, even without manufacture or sale, is actionable infringement.<sup>46</sup> Although further noting that the word "use," as it occurs in § 271(a), "has never been taken to its utmost possible scope," the court rejected Bolar's argument that its intended use of flurazepam hcl fell within the experimental use exception.<sup>47</sup> The court determined that the experimental use exception is "truly narrow" and should not be expanded under the circumstances of the case.<sup>48</sup> Applying the reasoning of *Pitcairn*, which stated that "[t]ests, demonstrations, and experiments... [which] are in keeping with the legitimate business of the... [alleged infringer]" are infringements for which "[e]xperimental use is not

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<sup>44</sup> See *Roche*, 733 F.2d at 861, 867.

<sup>45</sup> *Id.* at 861.

<sup>46</sup> See *id.* (citing 35 U.S.C. § 271(a) (1994); *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964); *Coakwell v. United States*, 372 F.2d 508, 510 (1967)). Section 271(a) states: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

<sup>47</sup> See *Roche*, 733 F.2d at 862.

<sup>48</sup> *Id.*

a defense,”<sup>49</sup> the court held that the experimental use doctrine does not apply to the “limited use of a patented drug for testing and investigation strictly related to FDA approval requirements during the last six months of the term of the patent.”<sup>50</sup> The court made a strong and eloquent statement of its interpretation of the law:

Bolar’s intended use of flurazepam hcl to derive FDA required test data is... an infringement of the [Roche] patent. Bolar may intend to perform “experiments,” but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimus*. It is no trifle in its economic effect on the parties, even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of “scientific inquiry,” when that inquiry has definite, cognizable, and not insubstantial commercial purposes.<sup>51</sup>

This language suggests that the Federal Circuit intended for the experimental use doctrine to be unavailable whenever a defendant’s research was motivated, even in part, by a commercial purpose.<sup>52</sup> In closing, the Federal Circuit addressed in detail two significant problems encountered by drug manufacturers as a result of FDA regulation. First, the court cited a study indicating that it could take from seven to ten years to obtain FDA approval for new drugs.<sup>53</sup> The

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<sup>49</sup> *Pitcairn*, 547 F.2d at 1125–26.

<sup>50</sup> *Roche*, 733 F.2d at 861.

<sup>51</sup> *Id.* at 863.

<sup>52</sup> See, e.g., Eisenberg, *supra* note 22, at 1023 (making this observation and noting that, as a practical matter, this could place severe limitations on the experimental use exception in fields of research of commercial significance, in which even academic research will often be motivated at least in part by commercial interest).

<sup>53</sup> See *Roche*, 733 F.2d at 864 (citing NATIONAL ACADEMY OF ENGINEERING, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 79–80 (1983)); see also Jeffrey P. Cohen, *The Beginnings: Laboratory and Animal Studies*, FDA CONSUMER (Nov. 1987), revised as reprinted in *FDA Consumer Special Report on New Drug Development in the United*

court noted that this delay in FDA approval whittled away at the length of the effective patent term. Second, the court stated that research-oriented drug manufacturers, by enjoining the use of patented drugs for testing purposes until their patents expired, could use the threat of a patent infringement claim to prevent competing uses of the patented invention by generic drug companies beyond the intended seventeen year statutory term.<sup>54</sup> After describing these problems, however, the court observed that it was not its place to resolve the conflict between the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>55</sup> and the Patent Act of 1952's respective policies and purposes.<sup>56</sup> Although noting the tension between the patent law and the drug approval laws, the court concluded that “[i]t is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. No matter how persuasive the policy arguments are for or against these proposed bills, the court is not the proper forum in which to debate them.”<sup>57</sup>

### III. ROCHE OVERRULED: THE LEGISLATIVE HISTORY AND INTENT

*States* (Jan. 1995), available in FDA, *The Beginnings: Laboratory and Animal Studies* (visited Jan. 18, 2000) <<http://www.fda.gov/fdac/special/newdrug/begin.html>>.

<sup>54</sup>See *Roche*, 733 F.2d at 864.

<sup>55</sup>21 U.S.C. §§ 301–92 (1982).

<sup>56</sup>See *Roche*, 733 F.2d at 863–64 (“We decline the opportunity here... to engage in legislative activity proper only for the Congress.”).

<sup>57</sup>*Id.* at 865 (“[I]t is not our job to apply laws that have not yet been written.” (quoting *Sony Corp. of America v. Universal City Studios, Inc.*, 104 S. Ct. 774, 796 (1984) (internal quotation marks omitted))); see also Timothy John McCoy, *FDA Medical Device Approval: The Noninfringing Experimental Use Defense Is Expanded: Eli Lilly & Co. v. Medtronic, Inc.*, 110 S. Ct. 2683 (1990), 14 HAMLINE L. REV. 201, 219–20 (1990).

UNDERLYING § 271(E)(1)

The Federal Circuit’s refusal in *Roche* to address the conflict between the FDA’s drug approval process and the patent law spurred debate within the pharmaceutical industry and among consumer groups.<sup>58</sup> In order to remedy distortions of the law and threats to the generic drug industry’s viability that the *Roche* holding was thought to create, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. This Act modified both the FDCA and the Federal Patent Code<sup>59</sup> and attempted to create a compromise between the conflicting interests of established, research-oriented manufacturers and emerging, production-oriented generic manufacturers.<sup>60</sup>

A.

*Regulatory Enigmas: Pre-1984 Pioneer and Generic Drug Manufacturer Conflicts*<sup>61</sup>

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<sup>58</sup>See J. Matthew Buchanan, *Medical Device Patent Rights in the Age of FDA Modernization: The Potential Effect of Regulatory Streamlining on the Right to Exclude*, 30 U. TOL. L. REV. 305, 318 (1999); Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 154 (1989).

<sup>59</sup>See Buchanan, *supra* note 58, at 314–15.

<sup>60</sup>See McCoy, *supra* note 57, at 220; see also James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 435 (1986); Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 291 (1985).

<sup>61</sup>Drugs and the companies that produce them are classified according to their approach to the market. “Pioneer” companies, also known as innovator companies, devote significant time and resources to the research and development of new drugs, also known as “pioneer” drugs, “breakthrough” drugs, or “name brand” drugs. “Generic” drug companies are companies that do not typically engage in novel research, but instead copy the active ingredients of pioneer drugs in order to compete with a name brand product in the marketplace. See Joseph P. Reid, *A Generic Drug Price Scandal: Too Bitter a Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 339 n.18 (1999). Because copying a product is significantly less expensive than developing a drug from scratch, generic drug manufacturers are able to offer their products to consumers at a considerable savings. See Ned Milenkovich, *Deleting the Bolar Amendment to the Hatch-Waxman Act:*

Before the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, manufacturers of generic forms of patented pharmaceuticals had to undergo the same lengthy regulatory approval process as pioneer drug companies.<sup>62</sup> This requirement presented efficiency losses due to redundancy and because generic drug manufacturers could not initiate the regulatory approval process before the expiration of the pioneer company's patent without risking liability for patent infringement.<sup>63</sup> "Consequently, there was no immediate competition in the marketplace following patent expiration, and the patent holder realized a de facto extension of the expired patent."<sup>64</sup> Thus, the intersection of the patent law and the FDA drug approval process created an unintended "grace period," during which pioneer drug manufacturers continued to enjoy de facto market exclusivity, even after the expiration of their patents.<sup>65</sup> Despite this grace period, pioneer drug companies also struggled with difficulties created by the FDA approval process, because large portions of their patent terms

*Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751, 752-53 & n.23 (1999).

<sup>62</sup>See, e.g., Thomas F. Poche, *The Clinical Trial Exemption From Patent Infringement: Judicial Interpretation of Section 271(e)(1)*, 74 B.U. L. REV. 903, 912 (1994) (observing that the FDCA imposed burdens on generic drug manufacturers because generic versions of previously approved pioneer drugs were considered "new drugs" for the purposes of FDCA applications). "As a result, generic drug manufacturers had to duplicate the expensive NDA process that the inventor and pioneering manufacturer had undergone." *Id.*

<sup>63</sup>See Buchanan, *supra* note 58, at 308; Reid, *supra* note 61, at 314 (observing that because of pioneer drug patents and FDA requirements for clinical trials, generic manufacturers faced delay in their ability to get products into the marketplace).

<sup>64</sup>Buchanan, *supra* note 58, at 308; see also *Roche*, 733 F.2d at 864 (stating that pioneer companies "gain for themselves... a de facto monopoly of upwards of two years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires").

<sup>65</sup>See *Eli Lilly & Co. v. Medtronic*, 496 U.S. 661, 670 (1990) ("[T]he patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained."); see also Buchanan, *supra* note 58, at 308.



were sacrificed to the FDA's premarket regulatory review of new drug products.<sup>66</sup> Because of the stricter FDA controls enacted in 1962, which mandated exacting clinical trials and an elongated review period, pioneer drug companies fought to maintain economic viability.<sup>67</sup> Pioneer productivity was reduced to "an average of seventeen new drugs annually between 1963 and 1972, and to twelve in 1980."<sup>68</sup> The pioneer drug companies struggled with the increased cost of development that resulted from the FDA's elaborate testing requirements.<sup>69</sup> The pioneer companies also experienced decreasing returns on investment, as the FDA approval process consumed greater portions of the seventeen year patent term.<sup>70</sup> As pioneer drug companies attempted to recoup these losses through raising prices, aggressively litigating their patent rights,<sup>71</sup> and lobbying legislatures for "antissubstitution" laws,<sup>72</sup> consumers endured higher pharmaceutical prices and decreased product choice.

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<sup>66</sup> See, e.g., Reid, *supra* note 61, at 313.

<sup>67</sup> See *id.* (observing that following the FDCA amendments of 1962, the pioneer drug industry "took a step backwards").

<sup>68</sup> *Id.*

<sup>69</sup> One study suggests that it requires twelve to nineteen years for a patentee to recover both initial investment cost and a reasonable rate of return on an invention. See Henry G. Grabowski & John M. Vernon, *A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development*, 3 MAN. & DECISION ECON. 36 (1982).

<sup>70</sup> See Alan D. Lourie, *A Review of Recent Patent Term Extension Data*, 71 J. PAT. OFF. SOC'Y 171, 174 (1989) (reviewing the time required to perform clinical testing and to obtain FDA approval for sixty-five patented human pharmaceuticals); see also Poche, *supra* note 62, at 912 ("Because the FDA approval process consumes one-third to one-half of the patent term for an average product, this substantially reduces the likelihood that an inventor will recoup her investment costs, and thus diminishes the incentive to invest."); Reid, *supra* note 61, at 314.

<sup>71</sup> See Keyack, *supra* note 58, at 152-53 (discussing the increased number of civil lawsuits for patent infringement by pioneer drug companies between 1962 and 1984).

<sup>72</sup> See *id.* at 153 n.42. "Antissubstitution" statutes prohibited pharmacists from substituting generic drugs for brand name drugs. See *id.*, Reid, *supra* note 61, at 314 & n.33.

Following the *Roche* decision, which acted as a impetus for change,<sup>73</sup> both pioneer and generic drug manufacturers called upon Congress to remedy the perceived failures of the marketplace caused by the intersection of the patent law and FDA regulations.<sup>74</sup> Consumer groups and generic drug manufacturers argued that generic drug manufacturers should have earlier access to the FDA approval process, in order to bring their products to market after the expiration of the pioneer drug patents. In turn, manufacturers of brand name pharmaceuticals lobbied Congress for extended patent terms, to compensate for the time that they expended on FDA clinical trials and approval.<sup>75</sup> “The goal of the pharmaceutical lobbyists was to induce passage of a bill that would allow restoration of portions of the patent life lost in the premarket regulatory review of new drug products (e.g., FDA approval procedures). Competing with this objective was that of the consumer groups which called for a quicker entry into the market for generic drug manufacturers.”<sup>76</sup>

B.

*Seeking Reconciliation Through the Drug Price Competition  
and Patent Term Restoration Act of 1984*

Through the Drug Price Competition and Patent Term Restoration Act of 1984, Congress attempted to minimize the amount of time between the expiration of a pioneer drug company’s patent and the availability of approved

<sup>73</sup>See Keyack, *supra* note 58, at 154–55 (citing the *Roche* decision as providing a political stimulus for both generic and pioneer drug manufacturers).

<sup>74</sup>See Poche, *supra* note 62, at 913 & n.78.

<sup>75</sup>See *id.* at 913 n.78.

<sup>76</sup>Christiansen, *supra* note 4, at 616; see also Wheaton, *supra* note 60, at 440.

generic competitors, while continuing to balance the needs of pioneer drug companies and their incentives to innovate.<sup>77</sup>The Act consists of two titles. Title I describes “Abbreviated New Drug Applications” (ANDAs),<sup>78</sup> and Title II addresses “Patent Term Restoration.”<sup>79</sup> 1. 35 U.S.C. § 156. — The first element of Title II of the DPCPTR Act is 35 U.S.C. § 156.<sup>80</sup>This provision arose out of Congress’s recognition that pioneer drug companies’ incentives to innovate were diminished because FDA premarket approval requirements reduced the effective patent life of their inventions.<sup>81</sup>In response to this problem, Congress enacted § 156, which extends the patent term for products that are subject to a regulatory review period before commercial marketing and use.<sup>82</sup>To qualify for a patent

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<sup>77</sup> See, e.g., Milenkovich, *supra* note 61, at 754–55 (describing three goals of the Drug Price Competition and Patent Term Restoration Act: “(1) encourage generic ‘competition’ in the pharmaceutical industry by streamlining the process of regulatory approval for generics, (2) stimulate investment in pharmaceutical research and development by restoring to the patent owner a part of the patent term consumed by regulatory delay, and (3) facilitate immediate competition in the marketplace upon patent expiration by securing for the generic industry an exemption from infringement activities relating to FDA submissions”) (internal citations omitted).

<sup>78</sup> Title I significantly altered 21 U.S.C. § 355, part of the FDCA, by creating a new process for obtaining abbreviated new drug approval. “Under this new system, any party meeting the statutory conditions could file an ANDA and would receive an answer from the FDA within 180 days. The conditions were specifically tailored to fit the generic drug industry: they essentially required an informational showing that the ANDA drug was similar or identical in all important respects to a pre-existing, FDA-approved drug, and a certification that the new drug would not infringe upon any pre-existing drug’s patent.” Reid, *supra* note 61, at 317 (internal citations omitted). Title I also established grounds upon which the FDA can reject an ANDA or withdraw ANDA approval in the interest of safety. See *id.* at 317–18. A full discussion of Title I of the Drug Price Competition and Patent Term Restoration Act and the ANDA process is beyond the scope of this essay. See generally PETER BARTON HUTT & JAMES C. MORRISON, ABBREVIATED NEW DRUG APPLICATIONS (1985); Brinckerhoff, *supra* note 12, at 643–45; Wheaton, *supra* note 60, at 458 (discussing the new ANDA procedure for gaining approval of generic drugs)

<sup>79</sup> See generally Rathe, *supra* note 30, at 632.

<sup>80</sup> 35 U.S.C. § 156 (1994).

<sup>81</sup> See Rathe, *supra* note 30, at 632–33.

<sup>82</sup> See H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 17–18 (1984) (stating that, because the effective life of patents has decreased because of Federal premarketing regulations, innovation has declined). Section 156 was expected to create a “significant, new incentive

term extension under § 156, a drug company must satisfy several requirements. “First, the term of the patent must not have expired before an application is submitted to the Commissioner for its extension. Second, the term of the patent must not have been extended previously, and the patented product must have been subject to a regulatory review period before its commercial marketing or use. Finally, the product must be an ‘approved product.’”<sup>83</sup>Section 156 contains the following list of “approved products”: “(A) A human drug product. (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.”<sup>84</sup>

2. *The Role of 35 U.S.C. § 271(e)(1)*. — The second element of Title II’s delicate balancing of interests is the codification of the experimental use doctrine as a defense to patent infringement claims in § 271(e)(1) of the Act.<sup>85</sup>This provision of the Drug Price Competition and Patent Term Restoration Act created an exception to the patent infringement statute that permits a manufacturer of a generic form of a patented drug to conduct activities that would otherwise constitute infringement as long as the activities are “solely for uses reasonably related to the development and submission of information to the which would result in increased expenditures for research and development.” H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 18 (1984).

<sup>83</sup>Rathe, *supra* note 30, at 633 (citing 35 U.S.C. § 156(a)(1)–(5)).

<sup>84</sup>35 U.S.C. § 156(f)(1). The maximum extension available under § 156 was limited to fourteen years of market exclusivity from the date of FDA approval, because Congress recognized that some of pioneer drug companies’ lost marketing time results from necessary development effort, rather than government delay. *See Engelberg, supra* note 7, at 390 n.4.

<sup>85</sup>*See Eli Lilly & Co. v. Medtronic*, 496 U.S. 661 (1990); *see also McCoy, supra* note 57, at 221.

FDA.”<sup>86</sup>Through its enactment of § 271(e)(1), Congress overruled the *Roche* decision.<sup>87</sup>Congress rejected the strong language and reasoning of the *Roche* case, stating that “experimental activity does not have any adverse economic impact on the patent owner’s exclusivity during the life of the patent.”<sup>88</sup>Congress hoped that § 271(e)(1) would enable generic drug manufacturers to use patented drugs to obtain premarketing approval, which would make less expensive generic equivalents of brand name drugs available to consumers eighteen months to two years earlier than under the system established by *Roche*.<sup>89</sup>Thus, in § 271(e)(1), Congress espoused a much narrower vision of proscribed commercial activity than that suggested by the Federal Circuit in *Roche*.<sup>90</sup>As a result, testing by generic drug companies prior to the expiration of a patent term, which would have been held infringing under *Roche*, was deemed permissible, despite the companies’ clear competitive purpose.<sup>91</sup>

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<sup>86</sup>35 U.S.C. § 271(e)(1).

<sup>87</sup>See Pub. L. No. 98-417, Title II, 98 Stat. 1585 (1984); H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 2, at 27 (1984) (stating that “[t]he provisions of [§ 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*”); H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 45–46 (1984) (same); see also Brinckerhoff, *supra* note 12, at 645; Rathe, *supra* note 30, at 632.

<sup>88</sup>H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 46, *reprinted in* 1984 U.S.C.C.A.N. 2679; see also H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 2, at 8, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692 (“The patent owner retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.”).

<sup>89</sup>See Brinckerhoff, *supra* note 12, at 645 (citing H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 2, at 29 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713).

<sup>90</sup>See Israelsen, *supra* note 24, at 464 & n.33.

<sup>91</sup>See Rathe, *supra* note 30, at 632.

Although it is clear that § 271(e)(1) was intended to overrule *Roche*, Congress did not provide much information about whether the provision was intended reach beyond the specific facts presented by that case.<sup>92</sup> As written, the exception appears to offer broad-sweeping protection to any putative infringer who uses a patented invention to acquire information required to be submitted under a federal law regulating drugs or veterinary biological products.<sup>93</sup> The legislative history of the provision, however, suggests that Congress was concerned with a smaller range of activities, a narrower class of infringers, and specific types of patented inventions.<sup>94</sup> For example, the House Judiciary Committee report stated that “the only activity that will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.”<sup>95</sup> The report of the House Committee on Energy and Commerce further elaborated:

The information which can be developed under this provision is the type which is required to obtain approval of the drug.... The purpose of Sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.<sup>96</sup>

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<sup>92</sup> See Brinckerhoff, *supra* note 12, at 648–49 (“Because Congress clearly expressed its intent to overrule *Roche*, it can be assumed that it intended at least these types of activities to fall within section 271(e)(1). Congress may not have contemplated the application of the statute to any other activities.”).

<sup>93</sup> See *id.* at 647–48 (“[The exception] appears to apply to any activity reasonably related to obtaining premarket approval, and to any patented invention that would be infringed in the course of conducting such activities.”).

<sup>94</sup> See *id.*

<sup>95</sup> H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 2, at 8, *reprinted in* U.S.C.C.A.N. 2686, 2692.

<sup>96</sup> *Id.* at 45, *reprinted in* U.S.C.C.A.N. 2647, 2678.

Similarly, although the statute does not facially restrict its applicability to any class of infringer, the legislative history suggests that the provision was drafted to benefit generic drug manufacturers alone. The legislative history describes the exception as providing that “it is not an act of patent infringement for a *generic drug maker* to... test a patented drug,”<sup>97</sup> and states that the provision is intended to enable “a *generic drug manufacturer*... [to] obtain a supply of a patented drug product during the life of the patent.”<sup>98</sup>

#### IV. Judicial Interpretation of the § 271(e)(1) Exemption for Experimental Use

Because of the ambiguity of § 271(e)(1)’s language and the apparent conflict between its stated provisions and its legislative history, courts have struggled to define its parameters. Several decisions interpreting section 271(e)(1), which highlight its indeterminacy, followed shortly after its enactment.<sup>99</sup>

##### A. The Scripps Cases: Range of Infringing Activities Protected Under § 271(e)(1)

1. *Scripps Clinic & Research Foundation v. Genentech Inc.* — The first published decision interpreting § 271(e)(1) arose in *Scripps Clinic & Research Foundation v. Genentech Inc.*,<sup>100</sup> a lawsuit involving several biotechnology patents

<sup>97</sup>H.R. Rep. No. 98-857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648 (emphasis added).

<sup>98</sup>*Id.* at 5, *reprinted in* 1984 U.S.C.C.A.N. 2689 (emphasis added).

<sup>99</sup>*See generally* McCoy, *supra* note 57, at 221–22 (cataloging decisions).

<sup>100</sup>231 U.S.P.Q. (BNA) 978, 979 (N.D. Cal. 1986).

on Factor VIII:C.<sup>101</sup> Scientists at Genentech began research to produce Factor VIII:C through recombinant DNA technology before the Scripps patents issued and continued these efforts after the patents issued.<sup>102</sup> After Genentech used Scripps's patented product, purified Factor VIII:C, to determine its amino acid sequence, clone the Factor VIII:C gene, and produce Factor VIII:C by recombinant DNA techniques, Scripps sued Genentech for patent infringement, seeking damages and an injunction against further use by Genentech of purified Factor VIII:C.<sup>103</sup> The court focused on the "solely for" language of § 271(e)(1) and refused to apply the experimental use exception to Genentech's activities because, although they might eventually lead to submission of data to the FDA, that was not the company's "sole purpose."<sup>104</sup> The court concluded that Genentech's use of purified Factor VIII:C therefore constituted infringement.<sup>105</sup>

2. *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.* — In *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*,<sup>106</sup> a case

*Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*,<sup>106</sup> a case

<sup>101</sup>The patents at issue in the case arose out of Scripps's development of a process for purifying and concentrating Factor VIII:C, a protein that plays an essential role in blood clotting, from human and animal blood plasma. The patents included claims to both the process of purifying Factor VIII:C and the concentrated Factor VIII:C product itself. See *Scripps Clinic & Research Foundation v. Genentech Inc.*, 666 F. Supp. 1379, 1383 (N.D. Cal. 1987); see also Eisenberg, *supra* note 22, at 1079–80.

<sup>102</sup>See *Genentech*, 666 F. Supp. at 1384.

<sup>103</sup>See *Genentech*, 231 U.S.P.Q. at 979.

<sup>104</sup>See *id.* at 980.

<sup>105</sup>See *id.* at 979–80. In a second decision, on renewed motion, the court reaffirmed its earlier interpretation of § 271(e)(1), holding that "a multiple purpose use of a patent invention was not immunized, where only one purpose was related to FDA testing." Israelsen, *supra* note 24, at 465–66 (citing *Genentech*, 666 F. Supp. at 1396). The court rejected Genentech's argument that all the purposes were "reasonably related" to meeting the reporting requirements of the FDA. It narrowly interpreted § 271(e)(1)'s legislative history as establishing that the only use permitted by the statute was testing to establish bioequivalency. See *id.*

<sup>106</sup>7 U.S.P.Q.2d (BNA) 1562 (D. Del. 1998).



which also involved Factor VIII:C, Baxter defended against Scripps’s charges of infringement, asserting that its activities were protected under § 271(e)(1). Although Baxter had used Factor VIII:C to generate data both for FDA premarketing approval and to submit to foreign regulatory agencies, the United States District Court for the District of Delaware denied Scripps’s motion.<sup>107</sup> The court stated that the *Genentech* court had interpreted § 271(e)(1) overly narrowly and without regard to the “reasonably related” language of the statute:

The question of law, then, is whether any foreign activities can be “reasonably related” to FDA approval. If not, then Baxter’s activities would fall outside of Section 271(e)(1) and Baxter’s defense would be insufficient.... [The *Genentech* court] was faced with this issue, but [it] interpreted the statute only to cover activities that were “solely related” to FDA approval and did not consider what acts are “reasonably related” to it.<sup>108</sup>

Such reliance on one element of the statute at the expense of its other elements was in error, the court argued. In conclusion, the court observed that § 271(e)(1)’s legislative history failed to “provide guidance” on the matter of interpretation and suggested that the doctrine needed to be “more fully developed before the Court... decide[s] it.”<sup>109</sup>

*B. Eli Lilly & Co. v. Medtronic, Inc.: Range of Inventions Protected Under § 271(e)(1)*

The *Scripps* cases highlight courts’ attempts to determine the range of infringing *activities* exempted under § 271(e)(1). But courts have also experienced

<sup>107</sup> See *Baxter*, 7 U.S.P.Q.2d at 1565.

<sup>108</sup> *Id.* at 1564–65 (noting that the “scope of section 271(e)(1)... has no clear answer”); see also Israelsen, *supra* note 24, at 466.

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

difficulty in determining the types of *products* that are exempt from patent infringement charges under § 271(e)(1). The plain language of the statute is not plain at all, but rather refers cryptically to “a patented invention” and “a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”<sup>110</sup>In 1990, the Supreme Court was called upon to determine the scope of the products exempted by § 271(e)(1) in *Eli Lilly & Co. v. Medtronic, Inc.*<sup>111</sup>In 1983, Eli Lilly’s predecessor in interest sued Medtronic in the United States District Court for the Eastern District of Pennsylvania seeking to enjoin Medtronic from testing and marketing an implantable heart defibrillator.<sup>112</sup>Medtronic called upon § 271(e)(1), claiming that its activities were “reasonably related to the development and submission of information” under the FDCA, and thus were exempted from infringement under the statute.<sup>113</sup>The district court rejected Medtronic’s argument, holding that § 271(e)(1) did not apply to the development and submission of information related to medical devices.<sup>114</sup> Although the court acknowledged that such devices are “patented inventions,” the sale of which is “regulated” by the FDCA, it interpreted § 271(e)(1) as providing an exemption for drugs only.<sup>115</sup>On appeal, the Court of

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<sup>110</sup>35 U.S.C. § 271(e)(1).

<sup>111</sup>496 U.S. 661 (1990). “This case presents the question whether 35 U.S.C. § 271(e)(1) (1982 ed., Supp. V) renders activities that would otherwise constitute patent infringement noninfringing if they are undertaken for the purpose of developing and submitting to the Food and Drug Administration (FDA) information necessary to obtain marketing approval for a *medical device* under § 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), 90 Stat. 552, 21 U.S.C. § 360e.” *Id.* at 663–64 (emphasis added).

<sup>112</sup>*See id.* at 664.

<sup>113</sup>*See id.*

<sup>114</sup>*See id.*

<sup>115</sup>*See Eli Lilly & Co. v. Medtronic, Inc.*, 5 U.S.P.Q.2d 1760, 1761 (E.D. Pa. 1987).

Appeals for the Federal Circuit reversed the lower court’s ruling, “holding that by virtue of § 271(e)(1), [Medtronic’s] activities could not constitute infringement if they had been undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the FDCA.”<sup>116</sup>The court determined that the § 271(e)(1) exemption is not limited to drugs, but extends as well to medical devices that are subject to FDA approval.<sup>117</sup>The Supreme Court granted certiorari, and, in a 6–2 decision,<sup>118</sup>affirmed.<sup>119</sup>Rather than considering the language of the individual statutory provisions separately, in his opinion for the Court, Justice Scalia relied on the structure of the Drug Price Competition and Patent Term Restoration Act as a whole,<sup>120</sup> and concluded that the phrase “patented invention” in § 271(e)(1) is “defined to include all inventions, not drug-related inventions alone.”<sup>121</sup>The Court rejected Eli Lilly’s contention that the statutory phrase “a Federal law which regulates the manufacture, use, or sale of drugs” referred only to those individual provisions of federal law that regulate drugs, rather

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<sup>116</sup>*Eli Lilly*, 496 U.S. at 664.

<sup>117</sup>*See Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

<sup>118</sup>Justice Scalia delivered the opinion of the Court, in which Chief Justice Rehnquist and Justices Brennan, Marshall, Blackmun, and Stevens joined. Justice Kennedy filed a dissenting opinion, in which Justice White joined. Justice O’Connor took no part in the consideration or decision of the case.

<sup>119</sup>*See Eli Lilly*, 496 U.S. at 679.

<sup>120</sup>*See id.* at 665–66; *see also* David J. Bloch, *If It’s Regulated Like a Duck... Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, 54 FOOD & DRUG L.J. 111, 113 (1999) (discussing the *Eli Lilly* decision and the scope of § 271(e)(1)).

<sup>121</sup>*Eli Lilly*, 496 U.S. at 665 (citing 35 U.S.C. § 100(a) (“When used in this title unless the context otherwise indicates... [t]he term ‘invention’ means invention or discovery.”)).

than to the *entirety* of any Act in which at least some of the provisions relate to drugs.<sup>122</sup> Instead, the Court adopted Medtronic’s broader reading, concluding that “the phrase ‘a Federal law which regulates the manufacture, use, or sale of drugs’ more naturally summons up the image of an entire statutory scheme of regulation.”<sup>123</sup> This reading, the Court asserted, was supported by the historical meaning of the phrase “a Federal law,” which typically refers to an entire act or scheme of regulation, rather than to individual provisions of an act.<sup>124</sup> The Court also noted that if Congress had intended to refer only to drug products in the statute, then there were “infinitely more clear and simple ways of expressing that intent and it is hard to believe the convoluted manner petitioner suggests was employed would have been selected.”<sup>125</sup> Because he believed that the text of the provision was “not plainly comprehensible on anyone’s view,”<sup>126</sup> however, Justice Scalia next considered the structure of the statute as a whole.<sup>127</sup> Justice Scalia concluded that the Drug Price Competition and Patent Term Restoration Act of 1984 was “designed to respond to two unintended distortions of the

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<sup>122</sup> *See id.* at 665–66. Under Eli Lilly’s interpretation, products regulated under the drug and veterinary biologics provision of the FDCA would be eligible for § 271(e)(1) exemption, but those regulated under the Act’s other provisions would not. Therefore, Medtronic’s submission of information under 21 U.S.C. § 360(e), which dealt with devices, not drugs, would not be shielded from a patent infringement action. *See Bloch, supra* note 120, at 113.

<sup>123</sup> *Eli Lilly*, 496 U.S. at 666.

<sup>124</sup> *See id.* at 666–67.

<sup>125</sup> *Id.* at 667. For example, the provision might have read: “It shall not be an act of infringement to make, use, or sell a patented drug invention... solely for uses reasonably related to the development and submission of information required, as a condition of manufacture, use, or sale, by Federal law.” *Id.*

<sup>126</sup> *Id.* at 669. The Court ignored the legislative history of the provision, asserting that it “shed[] no clear light.” *Id.*

<sup>127</sup> *See id.*

seventeen-year patent term produced by the requirement that certain products must receive premarket regulatory approval”.<sup>128</sup>

First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the “clock” on his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted infringement... even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval. Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentees de facto monopoly would continue for an often substantial period until regulatory approval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.<sup>129</sup>

Because the Drug Price Competition and Patent Term Restoration Act sought to eliminate this distortion from both ends of the patent period, the Court concluded that the patent term extension provisions of the Act should apply to all FDCA-regulated products, whether drugs or devices.<sup>130</sup> The Court found further support for this interpretation from the textual indications of §§ 201 and 202 of the Drug Price Competition and Patent Term Restoration Act, because the two sections contain complementary omissions and inclusions. “Interpreting § 271(e)(1) as the Court of Appeals did here appears to create a perfect ‘product’ fit between the two sections. All of the products eligible for a

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<sup>128</sup> *Id.*

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

<sup>130</sup> *See id.* at 671–73.

patent term extension under § 201 are subject to § 202, since all of them — medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products — are subject to premarket approval under various provisions of the FDCA... or under the [Public Health Service]<sup>131</sup> Act.”<sup>132</sup> Because the sections of the statute appear to be intended to balance each other, the Court concluded that products that gain the benefits of § 201 should also be subject to the limitations of § 202, and vice versa. As a result, it held that medical devices are included in the § 271(e)(1) exemption from patent infringement.<sup>133</sup> Writing in dissent, Justice Kennedy, with whom Justice White joined, argued that the majority opinion applied a meaning to § 271(e)(1) that was contrary to the most plausible reading of the statute.<sup>134</sup> Justice Kennedy proposed that § 271(e)(1)’s text should be read narrowly, because it explicitly identifies drugs, while failing to mention any other type of invention.<sup>135</sup> Justice Kennedy believed that it would be inappropriate to expand § 271(e)(1)’s exemption to include a broader range of products, merely because they are regulated under the same statute that regulates drugs.<sup>136</sup>

C.

*Scripps Revisited: Intermedics, Inc. v. Ventritex, Co. and*

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<sup>131</sup>58 Stat. 682, as amended, 42 U.S.C. § 201, et. seq.

<sup>132</sup>*Eli Lilly*, 496 U.S. at 673–74.

<sup>133</sup>*See* Bloch, *supra* note 120, at 115.

<sup>134</sup>*See Eli Lilly*, 496 U.S. at 679 (Kennedy, J., dissenting).

<sup>135</sup>*See id.* at 680.

<sup>136</sup>*See id.*

Telectronics Pacing Systems, Inc. v. Ventritex, Inc.

After the Supreme Court extended the scope of § 271(e)(1) beyond generic drugs to medical devices and other products subject to an FDA approval process in *Eli Lilly*, courts' interpretation of the scope of infringing activities protected by the provision underwent a similar expansion.<sup>137</sup>In the *Ventritex* cases, plaintiffs brought suit against Ventritex for allegedly infringing their patents on implantable pacemakers.<sup>138</sup>Ventritex defended by claiming exemption under § 271(e)(1), because it was a potential manufacturer of a patented medical device subject to the FDA approval process. These cases presented the United States District Court for the Northern District of California with an opportunity to reevaluate its stance in the “solely for” versus “reasonably related” debate and offered the Federal Circuit its first opportunity to address the issue.

1. *Intermedics, Inc. v. Ventritex, Co.* — In *Intermedics, Inc. v. Ventritex, Co.*,<sup>139</sup>the plaintiff accused Ventritex of engaging in a broad range of infringing activities, including selling the patented devices in the United States, where the devices were used in clinical trials; making and selling the patented devices to international distributors, where the distributors resold them to FDA-approved clinical investigators; permitting testing of the devices by German officials, where testing was a prerequisite to German import approval; testing the devices

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<sup>137</sup>See Bloch, *supra* note 120, at 121.

<sup>138</sup>See *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1272 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (unpublished opinion); *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 19 U.S.P.Q.2d (BNA) 1960 (N.D. Cal. 1991), *aff'd*, 982 F.2d 1520 (Fed. Cir. 1992).

<sup>139</sup>775 F. Supp. 1269 (N.D. Cal. 1991).

in Germany, where the test results were submitted to the FDA; and demonstrating the devices at trade shows.<sup>140</sup> At trial, Intermedics claimed that Ventritex could not use its clinical trial data, gathered under the protection of § 271(e)(1), for such “collateral activities,”<sup>141</sup> because they were not “solely for uses reasonably related” to obtaining FDA approval.<sup>142</sup> The United States District Court for the Northern District of California rejected Intermedics’s argument and reevaluated the narrow interpretation of § 271(e)(1) that it had adopted in *Genentech*.<sup>143</sup> The court “invoked the ‘reasonably related’ language of section 271(e)(1) to exempt a broad range of activities from infringement,”<sup>144</sup> ultimately concluding that if it would have been reasonable for a party in the defendant’s position to believe that there was a “decent prospect” that the use in question would contribute to the generation of information relevant to the FDA approval process, then that use is protected under § 271(e)(1).<sup>145</sup> The court determined that Congress used the phrase “reasonably related” in order to communicate “its intention that the courts give parties some latitude in making judgments about

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<sup>140</sup> See *Intermedics*, 775 F. Supp. at 1282; see also Brinckerhoff, *supra* note 12, at 649.

<sup>141</sup> *Id.* at 1281; see also Poche, *supra* note 62, at 919. Ventritex also used its clinical data to solicit investment capital to fund additional trials, to prepare for production after the expiration of the patent term, and to apply for import approval and patent rights in foreign countries. See Poche, *supra* note 62, at 919.

<sup>142</sup> *Intermedics*, 774 F. Supp. at 1276.

<sup>143</sup> See *Scripps Clinic & Research Fund v. Genentech, Inc.*, 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (holding that collateral activities, not solely related to FDA approval, constitute infringement). Although the court did not explicitly repudiate its *Genentech* holding in *Intermedics*, it later did so in *Elan Transdermal Ltd. v. Cygnus Therapeutic Systems*, 24 U.S.P.Q.2d (BNA) 1226, 1232–33 (N.D. Cal. 1992), in which it adopted the *Intermedics* court’s interpretation of § 271(e)(1) and overruled its earlier interpretation in *Genentech*.

<sup>144</sup> Brinckerhoff, *supra* note 12, at 649.

<sup>145</sup> *Intermedics*, 775 F. Supp. at 1280.



the nature and extent of the otherwise infringing activities that they would engage in as they sought to develop information to satisfy the FDA.”<sup>146</sup> “[T]he court vigorously resisted any attempt to limit [a defendant manufacturer’s] collateral use of data that was otherwise properly collected under the § 271(e)(1) exemption.”<sup>147</sup>

2. *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.* — The Federal Circuit had an opportunity to expand upon the debate over the “solely for” versus “reasonably related” language of § 271(e)(1) in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*<sup>148</sup> In *Telectronics*, Ventritex had conducted clinical trials on its version of Telectronics’s patented implantable defibrillators in order to obtain data required by the FDA.<sup>149</sup> After Ventritex used the results of these clinical trials for fundraising and displayed its device at medical conferences, Telectronics sued, arguing that Ventritex’s uses were not exempt under § 271(e)(1) because they were not “solely for uses reasonably related to FDA approval.”<sup>150</sup> Thus, the Northern District of California was called upon once again to address Ventritex’s use of clinical trial data to raise investment capital.<sup>151</sup> The

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<sup>146</sup>*Id.* at 1280.

<sup>147</sup>Poche, *supra* note 62, at 919. The Federal Circuit affirmed the *Intermedics* decision in an unpublished opinion, without substantial analysis of the scope of § 271(e)(1). See *Intermedics, Inc. v. Ventritex, Inc.*, 26 U.S.P.Q.2d (BNA) 1525, 1525–29 (Fed. Cir. 1993).

<sup>148</sup>982 F.2d 1520 (Fed. Cir. 1992). Because the Federal Circuit affirmed *Intermedics* in an unpublished decision, 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993), *Telectronics* was its first published decision addressing this debate. See Brinckerhoff, *supra* note 12, at 649 n.63.

<sup>149</sup>See *Telectronics*, 982 F.2d at 1521–22.

<sup>150</sup>*Id.* at 1522–23.

<sup>151</sup>See *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 19 U.S.P.Q.2d (BNA) 1960, 1960 (N.D. Cal. 1991).

district court adhered to the position that it had espoused in *Intermedics* and held that such collateral activity did not void § 271(e)(1)'s exemption.<sup>152</sup>

On appeal, the Federal Circuit conducted a two-step analysis of Ventritex's activities, first determining whether its activities fell within the definition of infringement set forth in § 271(a), and then determining whether its activities fell within the § 271(e)(1) exemption.<sup>153</sup> "The court found that Ventritex's demonstrations of its defibrillator at medical conferences were unauthorized uses of Telectronics's invention that would fall under section 271(a), but that they were exempt from infringement under section 271(e)(1) because of Ventritex's need to find qualified investigators to conduct clinical trials. The court characterized Ventritex's other activities as 'dissemination of... data developed for FDA approval,' which is not an act of infringement under section 271(a)."<sup>154</sup> The court flatly rejected Telectronics's assertion that Ventritex's use of its clinical data for non-regulatory purposes should place its activities outside of § 271(e)(1)'s scope. Because the data was initially gathered for FDA-approval purposes, the court determined that § 271(e)(1)'s exemption should remain available, despite Ventritex's use of the data for collateral fundraising activities.<sup>155</sup>

<sup>152</sup>*See id.*

<sup>153</sup>*See Telectronics*, 982 F.2d at 1523.

<sup>154</sup>Brinckerhoff, *supra* note 12, at 650.

<sup>155</sup>*See Telectronics*, 982 F.2d at 1523–24 ("[Section 271(e)(1) is not] revoked when the resulting data is later used for non-FDA reporting purposes.").

This interpretation of § 271(e)(1) was consistent with its legislative history, the court asserted, because through its statutory enactment, Congress intended to place generic drug manufacturers “in a position to market their products as soon as... legally permissible.”<sup>156</sup> The court presumed that this intent was sufficiently broad to encompass fundraising activities, because of the need of generic manufactures to “raise funds for developing and testing” their products.<sup>157</sup> The court concluded that preventing generic drug manufacturers from using their clinical data for “fundraising and other business purposes” would inhibit their ability to compete in the marketplace.<sup>158</sup> Therefore, the court refused to impose any limitation on collateral uses of clinical data initially developed for submission to the FDA.<sup>159</sup>

*D. Return to Eli Lilly: Abtox, Inc. v. Exitron Corp.*

Although *Eli Lilly* settled conclusively § 271(e)(1)’s applicability to medical devices, the Court’s reliance on § 201 of the DPCPTR Act to interpret the statutory framework created a new area of uncertainty.<sup>160</sup> “By relying on the impact of premarket approval requirements, with their attendant regulatory delays, in section 201 to fashion its interpretation of section 202, the Court opened the question of whether devices that are not required to go through

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<sup>156</sup> *Id.* at 1525.

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

<sup>158</sup> *Id.*

<sup>159</sup> See Brinckerhoff, *supra* note 12, at 650.

<sup>160</sup> See Bloch, *supra* note 120, at 115.

the most demanding premarket approval process can claim protection under section 202.”<sup>161</sup>Because the FDCA subjects various types of medical devices to different regulatory review requirements, it is unclear whether all classes of medical devices are subject to the same protection under § 271(e)(1).<sup>162</sup>

In *Abtox, Inc. v. Exitron Corp.*,<sup>163</sup> the District of Massachusetts held that Exitron’s use of the patent  
it concluded that it was bound by the broader holding, “which remains in force despite a potential conflict

<sup>161</sup>*Id.*

<sup>162</sup>*See id.* at 115–16. The FDCA establishes three classes of medical devices for the purpose of approval and regulation:

Class I devices, defined as those (1) for which general controls, such as the prohibitions on adulteration and misbranding, are sufficient to provide reasonable assurance of safety and effectiveness, or (2) if such assurance is not available, those devices that are not represented for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and which do not present a potential unreasonable risk of illness or injury;

Class II devices, defined as those for which the general controls used for Class I devices are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls, such as performance standards and postmarket surveillance, that will provide such assurance; and

Class III devices, which cannot be classified as either Class I or Class II devices because insufficient information exists to determine if the application of general or special controls will provide reasonable assurance of safety and effectiveness, and which are purported for use in supporting or sustaining life or for a use of substantial importance in preventing impairment of human health, or which prevent an unreasonable risk of injury.

*Id.* (citing 21 U.S.C. § 360c(a)(1)(A)–(C)).

<sup>163</sup>888 F. Supp. 6 (D. Mass. 1995).

<sup>164</sup>*See id.* at 9.

<sup>165</sup>*See id.*

<sup>166</sup>*Abtox v. Exitron*, 122 F.3d 1019 (Fed. Cir. 1997).

<sup>167</sup>*Id.* at 1028.

<sup>168</sup>*See id.* at 1027–30.

<sup>169</sup>*See id.* at 1029 (“Therefore, under the broad holding of *Eli Lilly*, all classes of medical devices fall within the plain meaning of section 271(e)(1). Nevertheless, under the Court’s narrower justification of statutory symmetry, only Class III devices fall within the section.”).

<sup>170</sup>*Id.*

<sup>171</sup>*Id.*

<sup>172</sup>*See Buchanan, supra* note 58, at 309. *Abtox* also reaffirmed the position, espoused in the *Ventritex* cases, that data acquired under § 271(e)(1) can be used for collateral purposes

## V. Conclusion: The Future of § 271(e)(1)

Since its enactment over fifteen years ago, courts have struggled to define the precise contours of § 271(e)(1)'s exemption from patent infringement in light of its often unedifying legislative history and statutory text.<sup>173</sup> Even after all this time, the scope of permissible noninfringing experimentation with patented inventions remains unclear. Nevertheless, the courts' broadening interpretation of § 271(e)(1),<sup>174</sup> which "currently allows competitor manufacturers of products regulated by the FDA under the FDCA... to legally conduct a wide array of otherwise infringing activities,"<sup>175</sup> suggests that generic drug companies will without sacrificing the provision's protection. See *Abtox*, 122 F.3d at 1030 (stating that the statute permits a would-be infringer to "use its data... for more than FDA approval" and that "alternative uses are irrelevant" to a defendant's ability to invoke the statute).

<sup>173</sup> See, e.g., Bloch, *supra* note 120, at 162 (observing that the "theme that runs through any examination of [§ 271(e)(1)] is the difficulties courts face in interpreting congressional intent in the face of vague statutory language").

<sup>174</sup> See, e.g., Coggio & Cerrito, *supra* note 11, at 347 (cataloguing the wide range of activities that courts have held fall within the safe harbor of section 271(e)(1):

- using the drug product to raise capital (*Intermedics*; *Telectronics*);
- authorizing publications describing product features (*Intermedics*);
- circulating study results to a potential licensee (*Elan Transdermal Ltd. v. Cygnus Therapeutics Systems*, 24 U.S.P.Q.2d (BNA) 1226 (N.D. Cal. 1992));
- demonstrating features of the drug product at scientific meetings and trade shows (*Intermedics*; *Telectronics*; *Chartex Int'l Plc. v. M.D. Personal Prods. Corp.*, 5 F.3d 1505, 1993 WL 306169 (Fed. Cir. 1993));
- acquiring import approval from a foreign government (*Intermedics*);
- arranging importation into a foreign country (*Chartex*);
- performing clinical studies for foreign regulatory agency clearance (*Elan Transdermal; NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 205–06 (D.N.J. 1994));
- obtaining foreign patents (*Intermedics*);
- manufacturing a product to generate data and creating stockpiles (*Intermedics; NeoRx*);
- selling a product to clinical investigators at a hospital (*Intermedics*);
- selling a product to international distributors (*Intermedics*);
- testing a product in a foreign country by a clinical investigator (*Intermedics; NeoRx*);
- testing by foreign company (*Intermedics*);
- demonstrating the drug to physicians and non-physicians (*Telectronics; Chartex*);
- conducting consumer studies (*Chartex*);
- describing clinical trials to investors and journalists (*Telectronics*);
- promoting a product to customers (*Abtox*); and
- shipping a product to a potential commercial partner (*NeoRx*).

<sup>175</sup> Buchanan, *supra* note 58, at 324. Furthermore, as long as the reasonably related requirement is met, the manufacturer need not actually submit the resulting information to the FDA

continue to gain in the coming years at the expense of pioneer drug companies.<sup>176</sup>By virtue of its expansive interpretation by the courts, § 271(e)(1) has placed an increasing strain on the ability of pioneer drug companies to innovate and compete with generic drug companies.<sup>177</sup>By seemingly ignoring the fact that it is far easier to copy a new drug than it is to invent one,<sup>178</sup>§ 271(e)(1) may skew drug manufacturers’ incentives and fail to provide adequate patent protection to for pioneer drug companies. “Strong patent protection gives the inventive entity, as well as others, the incentive to continue to invent knowing that their intellectual property will be secure while benefiting society.”<sup>179</sup>In the absence of such strong protection, pioneer drug companies, confronted both by the increased costs of innovation and increased encroachment of their patent terms under § 271(e)(1), may become less inclined to devote time and resources to pursuing innovative solutions to human ailments.

Section 271(e)(1)’s breadth should not be permitted to grow unchecked. If in order to obtain protection under section 271(e)(1). See *Abtox*, 122 F.3d at 1027. The drug manufacturer merely has to demonstrate a reasonable relation between his activities and the development and submission of information to the FDA in order to benefit under § 271(e)(1). See Buchanan, *supra* note 58, at 324.

<sup>176</sup>See, e.g., Milenkovich, *supra* note 61, at 770 (describing the “[b]right [f]uture for [g]enerics”).

<sup>177</sup>See, e.g., Reid, *supra* note 61, at 339.

<sup>178</sup>See Milenkovich, *supra* note 61, at 752.

<sup>179</sup>*Id.* at 753 (citing JOSEPH SCHUMPETER, CAPITALISM, SOCIALISM, AND DEMOCRACY 81–86 (1950)). If an inventor believes that his patent’s value would be eroded by section 271(e)(1), he may decide to keep his invention a trade secret instead of seeking patent protection. See Brinckerhoff, *supra* note 12, at 658 n.152. Such conduct would undermine the fundamental purpose of the patent system, which is intended to “promote the progress of... the useful arts” by granting incentives to inventors who disclose their inventions to the public. U.S. CONST., art. I, § 8, cl. 8.

the trend of broad-sweeping judicial interpretation continues, § 271(e)(1) may be interpreted to encompass an even broader range of inventions, new FDA regulations, or activities only peripherally related to compliance with FDA requirements.<sup>180</sup>The pharmaceutical industry currently stands alone in exempting infringers from liability for violations of patent exclusivity.<sup>181</sup>Given the rarity of a provision such as § 271(e)(1) in the patent law, the wisest course may be to restrict the breadth of the clinical trial exemption.

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<sup>180</sup>*See, e.g.*, Buchanan, *supra* note 58, at 329 (noting that § 271(e)(1) is not presently applied to protect activities associated with compliance with the FDA's current Good Manufacturing Practices (cGMP) or Good Laboratory Practices (GLP) for medical devices).

<sup>181</sup>*See id.* at 764–65.

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57. 21 U.S.C. § 355(j)(5)(B)(iv) (1994)
58. 21 U.S.C. § 360c(a)(1)(A)–(C)
59. 35 U.S.C. § 100(a)
60. 35 U.S.C. § 156 (1994)
61. 35 U.S.C. § 271(a) (1994)
62. 35 U.S.C. § 271(e)(1) (1994)
63. 35 U.S.C. § 271(e)(2)–(4) (1994)
64. 58 Stat. 682, as amended, 42 U.S.C. § 201, et. seq.
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