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In-House Research Tools and the Free Testing Safe Harbor from Patent Infringement for FDA-Related Activities

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by

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INTRODUCTION

The American patent system was founded on a balance between principles of disclosure and exclusivity. The government asks the inventor to provide a complete description of his invention in sufficient detail that others skilled in the area would understand and be able to practice the invention. In exchange, the government grants the inventor a temporary right to exclude all others from practicing the invention. This period of exclusivity allows the inventor to recoup his research expenses in developing the invention and provides additional financial incentives that reward innovation.

As federal agencies grew in both number and power, they began to affect the individual rights of the people. In the case of patent rights, federal agencies affected the balance between disclosure and exclusivity. The Food and Drug Administration (FDA) created regulations that altered the "effective" patent term for products subject to the Federal Food, Drug, and Cosmetic Act (FDCA). Under the FDCA, certain products are required to undergo testing and the data must be submitted to and approved by the FDA before the product can enter the market. As a result, there may be a lapse of up to ten years between the conception of the product and actual entry into the market. After obtaining FDA approval, the "effective" patent term would be shortened to ten years.[1] The inventor in this situation would make a full disclosure of the invention, but would only receive half the payoff due to this shortening distortion. The balance was upset.

In an effort to restore the balance, Congress passed the Hatch-Waxman Act ("the Act"). The Act serves two major purposes. First, it restores the portion of the patent term lost to FDA testing and approval. In other words, the Act remedies the shortening distortion of patent terms. Second, the Act allows infringement free testing of the patented invention during the

[1] This assumes a twenty year patent term.

patent term so long as the use is reasonably related to obtaining a federal approval. Generic drug companies must still obtain FDA approval before they can enter the market at the expiration of the pioneer patent. If Congress had only restored the patent term for the pioneers under the Act and had not granted a free testing safe harbor for FDA activities, this would have created an effectively lengthened patent term, as the pioneer patent holder would enjoy a monopoly after the patent expired while the generic brands awaited their FDA approvals. Therefore, the safe harbor provision is required to remedy the lengthening distortion of patent terms. Besides balancing the effective patent term, the free testing safe harbor also facilitates generic drugs getting to the market sooner, which saves money.

The Hatch-Waxman Act restores some of the balance between disclosure and exclusivity, although the free testing safe harbor seems to erode some of the rights of pioneer patent holders. The definition of "reasonably related" and "patented invention" hold the key to exactly what will happen to the balance in the future. In particular, Congress and the courts must decide which "patented inventions" fit under the free testing safe harbor from infringement. The question has recently been raised whether tools used in research qualify for infringement protection under the Hatch-Waxman Act. Although a recent case has arguably closed the door to claiming the free testing safe harbor for commercial research tools,[2] this paper will explore the qualification of in-house research tools for free testing in light of the Federal Circuit Court's decision. Part I details the *Roche Products* decision and the response of Congress in passing the Hatch-Waxman Act. Part II provides an overview of the case law interpreting the Hatch-Waxman Act and how courts have treated the text of the statute and the intent of Congress to qualify various products. Part III explores how the *Proveris* decision has left an opening for in-house research tools to claim the free testing safe harbor from

[2] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008).

infringement. Finally, Part IV analyzes the prudence in subjecting in-house research tools to the free testing safe harbor and discusses the potential arguments that proponents and critics of this action may make.

I. Roche Products and the Reaction From Congress

A. The Roche Products Decision

The Federal Circuit Court of Appeals considered an exemption from the patent laws then in force for the pursuit of FDA approval in *Roche Products, Inc. v. Bolar Pharmaceutical Co*.[3] The suit involved a commercially successful sleeping pill manufactured by Roche Products called Dalmane.[4] Bolar sought to produce the generic version of the drug after Roche's patent expired.[5] Bolar, in an effort to be the first generic producer to the market, did not wait for the patent to expire in 1984 to begin acquiring data for a submission to the FDA.[6] Bolar instead procured a sample of flurazepam hcl, the active ingredient in Dalmane, from a foreign manufacturer in mid-1983.[7]

The Court for the Eastern District of New York found that Bolar's use of the patented drug strictly for FDA approval purposes was both de minimis and experimental.[8] On appeal, the Federal Circuit disagreed with the district court, holding that 35 U.S.C. § 271(a) on its face prohibits making, using, or selling a patented invention during the term of the patent without consent of the patent holder.[9] The court found, and Bolar conceded, that applying the common law experimental use doctrine to this case would be an imprudent expansion of the current

[3] 733 F.2d 858 (1984).
[4] *Id.* at 860.
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] Roche Prods., Inc. v. Bolar Pharmaceuticals Co., 572 F. Supp. 255, 257-58 (E.D.N.Y. 1983).
[9] *Roche*, 733 F.2d at 861.

doctrine.[10] In *Whittemore v. Cutter* the court created the experimental use doctrine, holding that the use of a patented invention for a philosophical experiment, curiosity, or amusement is not an act of infringement and is instead an experimental use.[11] The Federal Circuit held that in the present case, Bolar crossed the experimental use line because its use was ultimately for business purposes, though the immediate use was generating test data.[12]

The court similarly dispensed with Bolar's public policy argument. Bolar argued that owners of pharmaceutical patents retain an impermissible monopoly for a period following the expiration of their patent while competitors pursue FDA approval.[13] The Federal Circuit refused to pass judgment on this issue and called on Congress to decide whether to rewrite the law in this area.[14]

B. The Congressional Response to Roche Products

Congress realized that both the government and the public would save money if it was easier for drug companies to bring generic drugs to market, and created legislation to accomplish this end.[15] In 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act").[16] The Hatch-Waxman Act made it easier for generic drug manufacturers to request approval from the FDA for their generic drugs by allowing them to piggy back on the FDA application filed by the pioneer patent holder and file an Abbreviated New Drug Application (ANDA).[17]

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[10] *Id.* at 862-63.
[11] 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).
[12] *Roche*, 733 F.2d at 864.
[13] *Id.*
[14] *Id.* at 865.
[15] Marlan D. Walker, *The Patent Research Tool Problem After* Merck v. Integra, 14 Tex. Intell. Prop. L.J. 1, 18 (2005).
[16] 35 U.S.C. § 271(e)(1) (2000).
[17] Walker, *supra* note 15, at 19.

The Hatch-Waxman Act also alleviated some legitimate concerns of pioneer drug manufacturers. Prior to the 1984 Act, drug manufacturers had spent up to the first ten years of their patent term obtaining data, submitting an application to the FDA, and awaiting FDA approval.[18] The Hatch-Waxman Act created a statutory remedy for this loss of patent term by allowing the patent holder to recover the portion of the patent term lost to pursuing approval from the FDA.[19] However, Congress did limit the possible term extension to five years.[20]

The most important section of the Hatch-Waxman Act was written after *Roche Products*. Before the *Roche Products* decision, the Hatch-Waxman Act did not address any free testing safe harbor from infringement for generic drug manufacturers.[21] After the decision, the Bolar Amendment was added to the Act, essentially reversing *Roche Products*.[22] The Bolar Amendment exempted from infringement making, using, offering to sell, or selling a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs."[23] Thus, the use by Bolar, though outside the reach of the experimental use exception because of its commercial purpose, would be immunized by the free testing safe harbor of the Hatch-Waxman Act.

II. Interpretation of the Hatch-Waxman Act

As with most legislation, what seemed like a straight-forward solution at the time the legislation was written soon became not so clear when interpreted by courts and applied to various fact situations. The Hatch-Waxman Act has been interpreted by many courts since its

[18] *Id*. at 17.
[19] 35 U.S.C. § 156 (2000).
[20] 35 U.S.C. § 156(g)(6)(A) (2000).
[21] Walker, *supra* note 15 at 20.
[22] DONALD K. CHISUM,, CHISUM ON PATENTS: A TREATISE ON PATENTABILITY, VALIDITY, AND INFRINGEMENT (1997 & Supp. 2005); *Id*.
[23] 35 U.S.C. § 271(e)(1) (2000).

enactment, some making incremental changes and others making sizeable leaps to the understanding and application of the Act.

A. Eli Lilly and Co. v. Medtronic, Inc.

The first major opportunity for the Supreme Court to interpret the Hatch-Waxman Act was in 1990.[24] Eli Lilly brought suit against Medtronic for infringement of an implantable cardiac defibrillator.[25] The Court used *Eli Lilly* as an opportunity to define whether Section 271(e)(1) only applies to drugs, or sweeps more inventions under its provisions.[26] Justice Scalia found that, in reading Section 271(e)(1) in conjunction with Section 100(a), it is clear that the phrase "patented invention" as used in Section 271(e)(1) is not limited to a drug invention.[27] Justice Scalia further found that, in the context of Section 271(e)(1), "a Federal Law" means "an entire statutory scheme of regulation."[28] Applied to this case, the Court held that Section 271(e)(1) makes the most sense if it applies to all patented inventions regulated under a federal law regulating drugs (the FDCA), not only drug inventions themselves.[29] However, the Court noted that neither interpretation was particularly clear.[30] This conflict in interpretation was further evidenced by Justice Kennedy's dissent, which took an opposing view of the meaning of the statute.[31]

[24] Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661 (1990).
[25] *Id.* at 664.
[26] *Id.* at 661.
[27] *Id.* at 665 (Section 100(a) states that the term "invention" means invention or discovery unless contradicted in the specific section). "It shall not be an act of infringement to make, use, or sell a *patented invention* . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (2000) (emphasis added).
[28] *Id.* at 666-67.
[29] *Id.* at 665-669.
[30] *Id.* at 669.
[31] *Id.* at 679-80 (Kennedy, J., dissenting). "When § 271(e)(1) speaks of a law which regulates drugs, I think that it does not refer to particular enactments or implicate the regulation of anything other than drugs." *Id.* at 680.

The Court found that the shortening and lengthening distortions apply equally to medical devices as they do to drugs.[32] That is, a medical device that requires FDA approval under the FDCA would experience both a shortening distortion of its patent term while the device is being approved and a lengthening distortion of its patent term while competitors are awaiting their FDA approval after the patent expires.[33] Justice Scalia stated that, to hold that the free testing safe harbor under Section 271(e)(1) only applies to drugs would contribute to the monopoly of medical device patent holders.[34] The device would enjoy the patent extension under Section 156 to remedy the shortening distortion, as the device is unquestionably subject to regulation under a federal law, but would not be subject to the free testing safe harbor under Section 271(e)(1) to remedy the lengthening distortion.[35] Therefore, the Court concluded that Sections 156 and 271(e)(1) are meant to be complementary and any product subject to the patent term extension under Section 156 should be subject to the patent term reduction via the free testing safe harbor under Section 271(e)(1).[36] Thus, the Supreme Court had decided the definition of "patented invention" in Section 271(e)(1) included at least everything covered by Section 156.[37]

B. Intermedics, Inc. v. Ventritex, Inc.

The Northern District of California considered the meaning of the phrase "reasonably related" in *Intermedics, Inc. v. Ventritex, Inc*.[38] Similar to *Eli Lilly*, this case also dealt with the alleged infringement of an implantable cardiac defibrillator.[39] Ventritex was conducting clinical trials, performing demonstrations at trade shows, and selling the defibrillator to

[32] *Id.* at 669-73.
[33] *Id.*
[34] *Id.* at 672-73.
[35] *Id.*
[36] *Id.* at 673-74.
[37] *Id.* at 674.
[38] 775 F. Supp. 1269 (N.D. Cal. 1991).
[39] *Id.* at 1272.

hospitals and distributors before the Intermedics patent expired.[40] Intermedics brought suit and Ventritex claimed the free testing safe harbor of Section 271(e)(1) protected them from infringement.[41]

Intermedics argued that Section 271(e)(1) should only apply to parties that intend to commercialize the product after, not prior to expiration of the pioneer patent.[42] The court sought to avoid an examination of Ventritex's intent, holding that it is the actual use, not the intent of the party that must be analyzed.[43] The court proceeded to parse the statutory language, noting that Congress was careful to use the word "use" rather than the word "purpose" to show an intent that any test to determine whether the exemption applies be objective.[44] The court further reasoned that the words "reasonably related" in the statute give additional support to an objective test.[45] The court added the common sense argument that any activity immunized by the statute would ultimately have a business purpose.[46] To test whether the exemption applied, the court asked whether the uses are '"solely . . . reasonably related to the development and submission of information' to the FDA."[47] The court then announced a test to determine whether the use was "reasonably related."[48] The key question in this inquiry was whether the use would have been

> reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product.[49]

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[40] *Id.* at 1282.
[41] *Id*. at 1272.
[42] *Id.* at 1273.
[43] *Id.* at 1272-75.
[44] *Id.* at 1278.
[45] *Id.* at 1279.
[46] *Id.* at 1279-80.
[47] *Id.* at 1280.
[48] *Id.*
[49] *Id*.

Utilizing these tests, the court found that all of Ventritex's activities were immunized by Section 271(e)(1).[50]

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

The Federal Circuit confronted the meaning of "reasonably related" as it is used in Section 271(e)(1) in Telectronics Pacing Systems, Inc. v. Ventritex, Inc.[51] In 1989, Ventritex conducted clinical trials of an implantable defibrillator to obtain operational data for submission to the FDA.[52] Ventritex also displayed the device at medical conferences to non-physicians and described the trials to journalists and potential investors for the purpose of acquiring funding for manufacturing equipment and additional clinical trials.[53]

The court recognized the need for fundraising to conduct clinical tests even before information may be gathered to submit to the FDA.[54] This need is especially critical for medical device manufacturers who are unable to shorten the time required for FDA submission activities by filing an abbreviated application (ANDA) for FDA approval based on the submission of the pioneer product.[55] The court opined that the intent of Congress was "to allow competitors to be in a position to market their products as soon as it was legally permissible."[56] The court found the uses at issue fit the meaning of the statute, as the Congressional intent included allowing uses of patented inventions "for uses reasonably related to clinical trial purposes."[57]

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[50] *Id.* at 1289.
[51] 982 F.2d 1520 (Fed. Cir. 1992). "It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses *reasonably related* to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (2000) (emphasis added).
[52] *Id.* at 1521.
[53] *Id.* at 1521-22.
[54] *Id.* at 1525.
[55] *Id*. For a description of the ANDA process, *see* Walker, *supra* note 15 at 19.
[56] *Id*.
[57] *Id*.

D. Abtox, Inc. v. Exitron Corp.

At issue in the *Abtox* case was an apparatus and method for sterilizing medical devices using plasma gas.[58] The invention involved exciting the plasma gas to a point at which the gas emitted light, charged particles, and active components that bombard the medical device, thereby sterilizing it.[59] Exitron claimed that its limited use of the patented invention was to obtain data necessary for a submission to the FDA, and therefore was protected under Section 271(e)(1).[60] Abtox alleged that the purpose of Exitron's use was not FDA approval, but rather to promote the sterilizer to potential customers and persuade them to purchase the rights to the product.[61] Moreover, Abtox argued that Section 271(e)(1) does not apply to Class II medical devices like the sterilizer.[62]

The court initially cited *Eli Lilly* and summarized the decision of the Supreme Court that Section 271(e)(1) applies to medical devices as well as drugs.[63] Abtox attempted to distinguish the *Eli Lilly* decision based on the difference between Class II and Class III medical devices.[64] Abtox argued that because *Eli Lilly* involved a cardiac defibrillator, a Class III medical device that required much more extensive FDA pre-market approval, as opposed to the sterilizer at issue in the present case, a Class II medical device that enjoyed an abbreviated FDA approval process, *Eli Lilly* did not mandate the application of Section 271(e)(1).[65] Under Justice Scalia's reasoning in *Eli Lilly*, Sections 156 and 271(e)(1) are complementary, as both are needed to properly adjust the patent term.[66] However, in *Abtox*, the Class II medical device

[58] Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1020-21 (Fed. Cir. 1997).
[59] *Id.* at 1021.
[60] *Id.* at 1027.
[61] *Id*.
[62] *Id.* at 1027-28.
[63] *Id.* at 1028.
[64] *Id*.
[65] *Id*.
[66] *See supra* Part III.A.

was not eligible for a patent term extension under Section 156 because Class II devices are not required to undergo the more extensive FDA approval that Class III devices are required to meet.[67] Therefore, Abtox reasoned, to apply Section 271(e)(1) without Section 156 would be incongruous and effectively shorten the patent term of Class II devices.[68]

The Federal Circuit was sympathetic to Abtox's plight, but ultimately held that the Supreme Court's broader ruling in *Eli Lilly* governed wherein the statute includes all medical devices regardless of class.[69] The court noted that there will be occasions where only one of Sections 156 and 271(e)(1) apply, but the Supreme Court explicitly accepted this result in *Eli Lilly*.[70] The court continued that it must respect both the *Eli Lilly* decision and the statutory language, which does not distinguish between medical device classes.[71]

Finally, the Federal Circuit Court relied on *Telectronics* in disposing with Abtox's argument based on the "reasonably related" statutory language.[72] The court held that Abtox's intent and purpose for the data are irrelevant to a Section 271(e)(1) analysis, and as long as the testing is "reasonably related to obtaining FDA approval," the court will not consider alternative uses for the data.[73]

E. Infigen, Inc. v. Advanced Cell Technology, Inc.

The Federal Court for the Western District of Wisconsin looked to the narrow holding from *Eli Lilly* that Sections 156 and 271(e)(1) are complementary in a 1999 case.[74] *Infigen* involved the use of a patented method for the artificial stimulation of embryonic development

[67] *Abtox*, 122 F.3d at 1029.
[68] *Id*.
[69] *Id.*
[70] *Id*.
[71] *Id*.
[72] *Id.* at 1030.
[73] *Id.*
[74] Infigen, Inc. v. Advanced Cell Technology, Inc., 65 F. Supp. 2d 967, 979-81 (W.D. Wis. 1999).

in cows.[75] Advanced Cell argued that it was using Infigen's patented embryo development method to develop a product that would require FDA approval, which brings them under the 271(e)(1) free testing safe harbor from infringement.[76]

The court rejected Advance Cell's argument, focusing on Justice Scalia's complementary reasoning from *Eli Lilly*.[77] The district court held that Sections 156 and 271(e)(1) are meant to be read together and "[Section] 271(e)(1) applies only to those patents [to be extended under Section] 156(a)(4) and (5)."[78] The court stated that no cases had been cited to it, nor had it found any cases that would apply Section 271(e)(1) to a method or product not subject to Section 156.[79] The court then cited both *Abtox* and *Eli Lilly* in support of this proposition,[80] which completely contradicted the holding in *Abtox* and ignored part of the *Eli Lilly* opinion.[81] Unfortunately, the court never reached the question of whether Advanced Cell's activities were "reasonably related" to obtaining an FDA approval because the court disposed of the case based solely on the complementary reasoning from *Eli Lilly*.[82]

F. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.

The Southern District of New York interpreted the terms "patented invention" and "reasonably related" in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*[83] Rhone-Poulenc owned a patent covering a process for preparing the drug taxol and four intermediates used in the process.[84] These intermediates were used by Rhone-Poulenc both in the process of

[75] *Id*. at 969-70.
[76] *Id.* at 980.
[77] *Id*.
[78] *Id.*
[79] *Id*.
[80] *Id*.
[81] *See supra* Part III.C.
[82] *Infigen,* 65 F. Supp. 2d at 981.
[83] No. 95-Civ.-8833, 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001).
[84] *Id.* at *1.

preparing taxol and to make other intermediates or products in the claimed process.[85] Bristol-Myers used the claimed intermediates in research on taxol analogs.[86] Bristol-Myers claimed the protection of Section 271(e)(1) because its research involving the intermediates was solely for uses related to the submission of information to the FDA.[87] Rhone-Poulenc responded by arguing that the intermediates were not a "patented invention" under Section 271(e)(1).[88] Rhone-Poulenc made the same argument to define "patented invention" as Justice Scalia in *Eli Lilly*, that Sections 156 and 271(e)(1) are complementary and only products covered by the Section 156 patent term extension should be subject to the free testing safe harbor of Section 271(e)(1).[89] Since the intermediates were not eligible for the patent term extension under Section 156, Rhone-Poulenc argued that they were not a "patented invention" within the meaning of the statute and should not be subject to Section 271(e)(1).[90]

The district court initially advanced a textual argument, noting that nothing in the statute evidences a Congressional intent that Sections 156 and 271(e)(1) be perfectly complementary.[91] Without this Congressional intent, the court looked to other parts of the statute to find that the term "patented invention" applies to all patented inventions.[92] As support, the district court cited *Abtox* and *Chartex International PLC v. M.D. Personal Products Corp*., two cases in which a patented invention had been subjected to Section 271(e)(1), but not Section 156.[93] These cases involved Class I and Class II medical devices that were not subject to sufficient preclinical testing to obtain the statutory patent term

[85] *Id*.
[86] *Id*.
[87] *Id.* at *2.
[88] *Id*.
[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] *Id*.
[93] *Rhone-Poulenc*, 2001 WL 1512597 at *2-3; 5 F.3d 1505 (Fed. Cir. 1993).

extension, but were still subject to the free testing safe harbor of Section 271(e)(1).[94] Moreover, the court rejected Rhone-Poulenc's argument based on *Infigen* as misplaced, noting that the district court in that case must have misread *Abtox* to conclude that Sections 156 and 271(e)(1) are perfectly complementary.[95]

Finally, the court turned to the issue of whether Bristol-Myers' use was "reasonably related" to preparing a submission under a federal law within Section 271(e)(1).[96] The court used the *Intermedics* test[97] to find that Bristol-Myers' use of the patented intermediates was reasonably related to the submission of information under a federal law.[98] The court found particularly relevant the fact that Bristol-Myers' research was focused on finding a replacement for Taxol once the patent on the drug expired.[99]

G. Merck KGaA v. Integra Lifesciences I, Ltd.

In 2005, the Supreme Court heard a case defining the "reasonably related" boundary line involving a peptide used in biotechnology research.[100] Integra owned patents related to the tripeptide sequence known as the "RGD peptide."[101] Merck began funding research by Dr. David Cheresh relating to angiogenesis, the process by which new blood vessels grow from existing blood vessels.[102] Dr. Cheresh used the RGD peptide to develop three closely related peptides, and established one that Merck decided to pursue for regulatory approval.[103] Integra brought suit, claiming that Merck, the Scripps Research Institute (the location where research

[94] *Rhone-Poulenc*, 2001 WL 1512597 at *3.
[95] *Id.* at *3 n.5.
[96] *Id.* at *4.
[97] *See supra* Part II.B.
[98] *Rhone-Poulenc*, 2001 WL 1512597 at *4.
[99] *Id.*
[100] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
[101] *Id.* at 197.
[102] *Id.*
[103] *Id.* at 198-99.

was conducted), and Dr. Cheresh infringed the patents owned by Integra related to the RGD peptide.[104]

The Federal Circuit Court of Appeals unanimously found that Integra's patents covered the peptides developed by Dr. Cheresh and, by a divided panel, found that Section 271(e)(1) did not harbor the three defendants from infringement because their activities were "not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."[105] The court held that the FDA is not interested in the "hunt for drugs," but rather it seeks information regarding a drug that is actually submitted for regulatory approval.[106] In taking a narrow view of Section 271(e)(1), the court found that activities not directly producing FDA information strain the meaning of the statute,[107] as "reasonably related" to FDA approval did not, in the court's opinion, embrace all phases of research simply because the end product will require FDA approval.[108] The Federal Circuit expressed concern that expanding the free testing safe harbor under Section 271(e)(1) to these ends would threaten the rights of research tool patent holders because research tools are used to identify viable drug candidates and facilitate further research, both uses that would fit within an expanded scope of the statute.[109] Judge Newman argued in dissent for a resurrection of the common law research exemption.[110] She claimed that this exemption would not swallow research tools because of the fundamental difference between "use of an existing tool in one's research [and] study of the tool itself."[111]

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[104] *Id.* at 200.
[105] *Id.* at 201; Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 866 (Fed. Cir. 2003), *rev'd*, 545 U.S. 193 (2005).
[106] *Id*.
[107] *Id*.
[108] *Id.* at 867.
[109] *Id*.
[110] *Id.* at 874-76.
[111] *Id.* at 878.

The case was appealed to the Supreme Court, where Justice Scalia wrote the majority opinion. From the outset of the opinion, Justice Scalia made it clear that "[Section] 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA."[112] The Court found no valid reason 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."[113] This expansive reading of Section 271(e)(1) included information not expressly requested by the FDA, but that would give the FDA a more complete picture of the drug's effects and allow an FDA investigator to make an informed decision whether to allow the proposed trial to move forward.[114]

Justice Scalia agreed with the Federal Circuit majority that experimenting on a compound without any intent or reasonable expectation of submitting information to the FDA would not qualify for the free testing safe harbor under Section 271(e)(1).[115] However, Justice Scalia did not find that this premise necessarily prohibited free testing safe harbor protection for activities that do not ultimately result in an FDA submission due to the inherent uncertainty of when research is initiated.[116] The test announced by the Court is whether a researcher "has a reasonable basis for believing that a patented compound may work . . . and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA."[117] Similarly, the Court noted that research producing data not ultimately submitted to the FDA is not automatically placed outside of the Section 271(e)(1) free testing safe harbor.[118] In

[112] *Merck*, 545 U.S. at 202.
[113] *Id.*
[114] *Id.* at 203-04.
[115] *Id.* at 205-06.
[116] *Id.* at 206.
[117] *Id.* at 207 (quoting 35 U.S.C. § 271(e)(1)).
[118] *Id.* at 207-08.

addition to the uncertainty of research, the information required by the FDA may vary from case to case.[119] Although the Court declined to comment directly on the applicability of free testing under Section 271(e)(1) to research tools,[120] the opinion provides some general principles that may be extrapolated to this area.

H. Proveris Scientific Corp. v. Innovasystems, Inc.

The Federal Circuit Court directly addressed the applicability of Section 271(e)(1) to research tools in a 2008 case.[121] Proveris Scientific owned a patent covering an aerosol spray characterization system.[122] The system was used in research to allow calibrated measurement of aerosol spray drugs.[123] Hence, the system was used in obtaining FDA approvals for inhalers, but the system itself was not subject to FDA approval.[124] Innovasystems made an Optical Spray Analyzer (OSA) that was similarly not subject to FDA approval, but was used to measure nasal drug aerosol sprays in connection with submissions to the FDA.[125] Proveris brought an infringement claim, and Innovasystems asserted the 271(e)(1) free testing safe harbor.[126]

The court noted that the meaning of the terms "patented invention" and "reasonably related" were critical to this decision.[127] The court reviewed the two patent term distortions that the Hatch Waxman Act was designed to remedy, and found that, since Innovasystems's OSA is not itself subject to FDA premarket approval (the lengthening distortion), Congress did

[119] *Id*.
[120] *Id.* at 205 n.7.
[121] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008).
[122] *Id.* at 1258.
[123] *Id.*
[124] *Id.*
[125] *Id.* at 1259.
[126] *Id.* at 1259-60.
[127] *Id.* at 1261.

not intent the product to come under Section 271(e)(1).[128] Moreover, Proveris did not experience the shortening distortion because it was similarly not subject to the FDA approval process.[129] The court reasoned that its interpretation of "patented invention" complied with *Eli Lilly* because it took a complimentary view of Sections 156 and 271(e)(1).[130] The Federal Circuit Court proceeded to describe a "perfect product fit" when the term "patented invention" is interpreted to "include all products listed in [Section] 156(f)."[131] Finally, the argument by Innovasystems that its use was "reasonably related" to a submission to the FDA was not addressed by the court, as the interpretation of "patented invention" was considered dispositive in the case.[132]

III. Proveris Leaves the Door Open to an In-House Research Exemption

Although *Proveris* came down against research tools being protected by Section 271(e)(1), it may have left the door open to in-house research tools used in pursuit of FDA approval. The *Proveris* case dealt with a company, Innovasystems, that sold its Optical Spray Analyzer exclusively to pharmaceutical companies and the FDA.[133] In its opinion, the court focused on the definition of "patented invention" in holding that Innovasytems was not protected by Section 271(e)(1), and did not even address whether Innovasystems' acts were "reasonably related" to an FDA approval under the statute.[134] A future court may be able to get around the "patented invention" interpretation of the *Proveris* court, focus on the definition of "reasonably related," and include in-house research tools under Section 271(e)(1).

[128] *Id.* at 1265-66.
[129] *Id*.
[130] *Id*.
[131] *Id*.
[132] *Id.* at 1266.
[133] Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1264 (Fed. Cir. 2008).
[134] *See supra* Part II.H.

First, the *Proveris* court anchored its interpretation of "patented invention" on the complementariness of Sections 156 and 271(e)(1) as announced in *Eli Lilly*.[135] The court reasoned that, in order to satisfy Congressional intent, the Section 271(e)(1) free testing safe harbor should include all products qualifying for a patent term extension under Section 156.[136] However, this principle has been less than clear in the cases preceding *Proveris*. In *Abtox*, the Federal Circuit Court acknowledged, but refused to apply the complementariness of Sections 156 and 271(e)(1) in holding that all medical devices are within Section 271(e)(1).[137] This effectively allowed Class II medical devices to suffer the free testing immunization of potentially infringing activities under Section 271(e)(1) while not gaining the beneficial patent term extension under Section 156. Both the *Abtox* court and the *Eli Lilly* Court explicitly accepted the premise that occasionally there will be a product that is subject to only one of the two sections of the statute, despite the seemingly inequitable results.[138] *Rhone-Poulenc* added to this line of judicial reasoning, as the court found no Congressional intent that Sections 156 and 271(e)(1) be perfectly complementary.[139] Moreover, the *Rhone-Poulenc* court found that the term "patented invention" in the statute means any invention, not just drug inventions.[140] The court in *Proveris* seems to have either missed these non-complementary applications of Sections 156 and 271(e)(1) or ignored them, similar to the court in *Infigen*.[141]

Second, an in-house research tool used in pursuit of FDA approval would fit well within the definition of "reasonably related" as established by case law. The *Intermedics* decision provides a test for the "reasonably related" language of the statute that asks whether the uses

[135] *See supra* Parts II.A and II.H.
[136] *See supra* Part II.H.
[137] *See supra* Part II.D.
[138] *See supra* Parts II.A and II.D.
[139] *See supra* Part II.F.
[140] *Id*.
[141] *See supra* Parts II.E and II.H.

are '"solely . . . reasonably related to the development and submission of information' to the FDA."[142] Justice Scalia's definition of "reasonably related" as announced in *Merck* provided the latest insight into the meaning of the language as it applies to Section 271(e)(1).[143] The Court only required that a researcher have a reasonable basis to believe the data gathered would be submitted to the FDA for the potentially infringing activities to be protected by Section 271(e)(1).[144] An in-house research tool used to detect and record data during research intended to culminate in an FDA submission and approval is "reasonably related" to FDA submission activities as defined by both *Intermedics* and *Merck*. A researcher pursuing FDA approval would necessarily have a reasonable basis to believe that the data gathered would result in a submission to the FDA, as that is the ultimate pursuit. Moreover, if the researcher was focused on pursuing FDA approval, his uses of patented research tools would be solely reasonably related to an FDA submission.

Third, an in-house research tool used in pursuit of FDA approval is arguably more "reasonably related" to an FDA approval than an "outside" research tool made and sold to pharmaceutical researchers by a commercial company. In the former scenario, the researcher is making his own tool and all of his activities are aligned and focused on the end product, an FDA approval. The researcher is not concerned with commercial exploitation of the tool. In the latter scenario, a company totally removed from the research is mass-producing research tools that may or may not be used in pursuit of FDA approval. The focus is no longer exclusively on the pursuit of FDA approval and has strayed to commercial gain directly linked to the research tool itself. Some companies may use the tool not for pursuing FDA approval, but for pure product development to detect which products are the most effective. Granted, the

[142] 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).
[143] *See supra* Part II.G.
[144] *Id*.

Eli Lilly decision allows alternative uses for research data as long as at least one use for the data is pursuit of FDA approval, but an "outside" research tool seems to be more towards the boundary line of "reasonably related" whereas an in-house research tool would fall more towards the interior of the definition. Therefore, *Proveris* has arguably left the door open to in-house research tools based on the definitions of "patented invention" and "reasonably related" to an FDA approval, as developed through case law.

IV. Arguments For and Against an In-House Research Tool Exemption

There are many arguments that can be made for and against the inclusion of in-house research tools in the free testing safe harbor of Section 271(e)(1). The following is an exploration of these arguments. To put a label on each side of the debate, arguments in favor of inclusion of in-house research tools in Section 271(e)(1) will be made by "proponents" and arguments against inclusion will be made by "critics."

A. Research Tools and the Twin Distortions

The purpose behind the enactment of Sections 156 and 271(e)(1) were to remedy two distortions in the patent term for "patented inventions" that were subject to a federal approval process.[145] As described earlier, the shortening distortion was an effective shortening of the patent term caused by the delay in obtaining federal approval.[146] This was compensated for by an automatic extension of the patent term in Section 156.[147] The lengthening distortion was an effective lengthening of the patent term caused by the delay in competitors obtaining federal approval.[148] This was remedied by the free testing safe harbor in Section 271(e)(1).[149]

[145] *See supra* Part II.B.
[146] *Id*.
[147] *Id*.
[148] *Id*.
[149] *Id*.

Research tools are generally not subject to federal approval. The tools are simply an avenue to obtain data that may be submitted for federal approval. Since research tools are not subject to federal approval, patent holders do not experience the shortening distortion while waiting for federal approval. Once a research tool is patented, or even before it is patented, it can immediately be placed in the commercial market and the patent owner may begin recouping the corresponding research investment in the tool. This lack of delay in entering the market concludes that research tools are not subject to the patent term extension of Section 156.[150]

Similarly, research tools do not experience the lengthening distortion due to competitors awaiting their own federal approval before they may enter the commercial market. Research tool competitors may enter the market immediately upon expiration of the pioneer patent. Courts have taken two different approaches to relating Sections 156 and 271(e)(1) in this situation. A court taking a purely complementary approach to Sections 156 and 271(e)(1) would conclude that since research tools do not qualify for patent term extensions under Section 156, they do not qualify for the free testing safe harbor under 271(e)(1). This approach was taken by the courts in *Infigen* and *Proveris*.[151] However, if a court takes the view of the court in *Abtox*, *Rhone-Poulenc*, or arguably *Eli Lilly*,[152] it may find that research tools qualify for free testing under Section 271(e)(1) because they satisfy the definitions of "patented invention" and "reasonably related" to FDA approval, even though they do not qualify for a patent term extension under Section 156. Despite the two judicial possibilities, critics of an in-house research tool exemption would conclude that since research tools experience neither of

[150] 35 U.S.C. § 156 (2000).
[151] *See supra* Parts II.E and II.H.
[152] *See supra* Parts II.A, II.D and II.F.

the twin distortions the Hatch-Waxman Act was intended to remedy, no research tool patent, in-house or otherwise, should be subject to the Section 271(e)(1) free testing safe harbor.

B. Does an In-house Research Tool Exemption Further the Original Public Policy?

The overarching public policy reason for the Hatch-Waxman Act was a money savings by facilitating the quick arrival of generic drugs to market once the pioneer patent expired.[153] The sooner in the process the generic drugs were commercially available, the sooner the American people and insurance companies would begin to save money by purchasing the generic versions of prescription medications. To this end, the Hatch-Waxman Act removed patent barriers to allow generic drug producers to freely test the drug during the life of the patent. There is a direct relationship between the action Congress took and the policy reasons for the action.

It may be argued that extending the Hatch-Waxman Act to cover in-house research tools would further the public policy reasons for the Act itself. Allowing drug companies to make their own research tools would decrease the cost of research and testing, and may ultimately hasten the arrival of the generic drug to market. This would result in a money savings for prescription drug purchasers felt earlier in the life of the particular drug.

Alternatively, it may also be argued that extending this legislation to research tools of any sort, even in-house research tools, is not in furtherance of the limited policy objectives of the Hatch-Waxman Act. The Act was intended to hasten the arrival of generic drugs to market once the pioneer patent expired. This means taking all reasonable action to allow the generic drug to be ready for market, but preventing profiting before the pioneer patent expired. If the Section 271(e)(1) free testing exemption from infringement were applied to research tools, it would overshoot the intended purpose of bringing generics to market quickly and allow all

[153] *See supra* Part I.B.

drug companies to enjoy using research tools without permission from or payment to the patent owner. This may lower drug prices, but the policy behind it would be lowering drug prices at any cost, which sweeps too broad for this legislation and may have other implications to innovation, which are discussed in the next section.

C. Loss of Incentive to Innovate in the Area of Research Tools

Congress and the courts must maintain a balance of two competing policy interests when considering including in-house research tools under the free testing safe harbor of Section 271(e)(1). The first was mentioned in the previous section, bringing generic drugs to market quickly after the pioneer patent expires.[154] The second competing policy interest is specific to the patent system and is maintaining the incentive to invent.[155] Proponents of an in-house research tool free testing exemption would argue that alleviating the cost of paying patent holders royalties to use their tools would not stymie innovation, but would rather foster advancement in many different areas of research. Expensive research tools have the effect of grinding research to a halt because the researcher first has to acquire the significant investment necessary to purchase the research tools, assuming the patent holder is not withholding the tool altogether to gain an advantage in the field.[156] Reducing this cost and not subjecting researchers to the will of the patent holder would allow companies to reallocate that part of their budget designated for funding research tools to further innovation and research.

Critics of an in-house research tool exemption would argue that inclusion would reduce the incentive to innovate that is at the core of our patent system. Since its inception the patent system has been based on an even exchange. The inventor provides a full disclosure of the

[154] *See* Walker, *supra* note 15 at 32.
[155] *Id.*
[156] Vihar R. Patel, *Are patented research tools still valuable? Use, intent, and a rebuttable presumption: a proposed modification for analyzing the exemption from patent infringement under 35 U.S.C. § 271(e)(1)*, 47 IDEA 407, 433 (2006-2007).

invention which allows others to fully understand exactly what the invention is and the technological advance involved. In exchange, the inventor obtains the right to exclude others from practicing his invention for a period of time. This system gives appropriate incentive for individuals to invent by rewarding them with the opportunity to recoup their research expenses and potentially experience a surplus financial gain. The system also fosters innovation by creating incentives for inventors to share their technology. Once a patent expires, that piece of technology falls into the public domain and other inventors are free to use and build on it. Critics would argue that if we take away this even exchange for research tools by allowing companies to make their own version free and clear, the effect would be the end of research tool development. The major driver of innovation is the prospect of financial gain from exclusivity. Without this potential, corporations will stop investing in research tool innovation because it would be impossible for them to recoup the expenses involved in research.

Critics would also argue that the government should not take patent rights away from one technology area without an adequate substitute, regardless of the public policy reasons. The Hatch-Waxman Act already affects the patent rights of some patent holders, but the safeguards put in place, including the automatic patent term extension under Section 156 and the "reasonably related to a federal regulatory approval" language in Section 271(e)(1), substantially protect the rights of the patent holder. The case of an in-house research tool exemption is very different. This would effectively take away all patent rights for research tool companies because their target market, researchers, would be able to look up the relevant patent, build their own research tool, and not pay the patent holder a dime. It is very important that the American people have affordable prescription drugs, but the cost in this case would be all future innovation in the field of research tools.

Critics would further argue that losing the incentive to innovate in the area of research tools would result in an increase in trade secret protection for research tool designs. Trade secrets provide protection for devices, formulas, and processes for as long as the secret is held in confidence.[157] Trade secrets provide incentive for the owner of the technology to resist disclosure, or he would lose his trade secret protection, and his monopoly on the technology. Therefore, not only would there be a lack of incentive to innovate in the area of research tools, but if any innovation were to occur, there would be an incentive to keep the innovation secret. This strays even farther from the fundamentals of the patent system in fostering innovation through disclosure.

Proponents of an in-house research tool exemption would respond that pharmaceutical companies and others that perform research on products requiring FDA approval would still have adequate incentive to move research tool technology forward. The FDA would still require the same data to approve a product. It would be the researchers' responsibility to satisfy the FDA requirements. In an effort to cut costs and become more efficient, companies would try to develop better tools to provide the required data. In addition to the FDA submission requirements, for some technologies, the furtherance of the technology itself depends on the development of research tools. In the field of biotechnology many intermediate elements, compounds, and peptides are used as research tools to discover new drugs.[158] In these cases, the researchers would be free to experiment and develop new research tools, and therefore new end products without being encumbered by the consideration of patent rights. Individual researchers and corporations alike would have incentive to make their research better through in-house research tool development.

[157] *See* Robert M. Sherwood, *Trade Secret Protection: Help for a Treacherous Journey*, 48 Washburn L.J. 67, 69 (2008).
[158] Patel, *supra* note 156 at 429.

D. Legislative History Arguments

Critics of an in-house research tool exemption would point to the legislative history of the Hatch-Waxman Act to argue that research tools were never intended to be covered by the legislation. The House and Senate debates focused on drugs, including the balance between the need to protect the rights of pioneer drug makers and the need to bring generic drugs to the public.[159] Congress never considered research tools or even medical devices as being part of the Hatch-Waxman Act.[160] Congress even stated that the purpose behind Section 271(e)(1) was to allow a generic drug manufacturer to get some of the patented drug to test during the life of the patent term.[161] None of the legislative history behind the Act shows that the inclusion of research tools was either intended or contemplated.[162]

Proponents of an in-house research tool exemption would respond by noting that, regardless of the legislative history of the Act, no language was added to the legislation itself to give effect to the legislative intent. For example, even though the House and Senate debates focused on discussions regarding drugs, no language appears in the Hatch-Waxman Act limiting its application to drugs.[163] Instead, Section 271(e)(1) employs language like "patented invention" and "reasonably related to a federal approval."

Proponents would further argue that even though medical devices may have not been discussed or considered by Congress, courts have held that medical devices are covered by the statute. In *Eli Lilly and Co. v. Medtronic* the Supreme Court held that Section 271(e)(1)

[159] Walker, *supra* note 15 at 35.
[160] *Id*.
[161] Patel, *supra* note 156 at 431.
[162] Although outside the scope of this paper, another issue is whether Congress or the courts should decide this question. Some may argue that since there is no evidence that Congress considered the applicability of the legislation to research tools, Congress should decide this issue through future legislation rather than leaving the decision to the courts.
[163] Walker, *supra* note 15 at 35.

includes medical devices, in that case an implantable defibrillator.[164] Again in *Abtox, Inc. v. Exitron Corp.*, the Federal Circuit Court affirmed the *Eli Lilly* decision and held that Section 271(e)(1) applies to all medical devices, regardless of their class.[165] Therefore, regardless of what Congress did or did not intend, courts have been interpreting the statute as though it applies to a wider range of inventions than just drugs. The seeming inconsistency of *Abtox* in that Section 271(e)(1) was applied to a Class II device without the complementary Section 156, gives even more credence to the proponents' argument. Even if a statutory construction does not seem to make intuitive sense, the court makes the final interpretation. It is the court that decides what is covered by Section 271(e)(1), regardless of how Congress would seem to have applied the statute.

Proponents may also argue that the cases from this line contain clues evidencing a disregard for the legislative history behind the statute. First, in *Eli Lilly*, Eli Lilly's main argument was that the legislative history showed an intent by Congress that only drugs be covered by the statute.[166] Justice Scalia dispensed with this argument, stating that it is one thing for the legislative history to only discuss drugs, but it is very different for the statute to actually state that it only applies to drugs.[167] He added that "[i]t is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history."[168] The second aversion to legislative history in this line of cases was in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*[169] In that case the Federal Circuit Court addressed another legislative history argument, noting that if a statute is clear, the plain meaning will govern. The court stated that

[164] *See supra* Part II.A.
[165] *Id.*
[166] Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 669 n.2 (1990).
[167] *Id.*
[168] *Id.* (quoting Pittston Coal Group v. Sebben, 488 U.S. 105, 115 (1988)).
[169] 982 F.2d 1520 (Fed. Cir. 1992).

while legislative history can assist when a statute is unclear, "when the legislature has clearly spoken the law, the court's duty is to enforce it as written."[170] The third case involving a legislative history argument was the decision out of the Southern District of New York in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*[171] The court dispensed with Rhone-Poulenc's legislative history argument, and added that the Supreme Court has cautioned against relying on the statements of a few members of Congress to prove the intent of the entire body in passing the law.[172] The court noted that the only reliable way to know the intent of the members of Congress who passed the law is to look at the words of the law itself.[173] Finally, the Federal Circuit Court decision in *Integra Lifesciences I, Ltd. v. Merck KGaA*[174] provides another example of a judge discounting the legislative intent behind the Hatch-Waxman Act. In dissent, Judge Newman noted that even though the original purpose of Section 271(e)(1) was to facilitate bringing generic drugs to market, courts have interpreted the statute more broadly.[175] Judge Newman reasoned that it was the interpretation of the courts that the Federal Circuit Court must apply in the case.[176]

From these four examples, the proponent of an in-house research tool exemption may argue that the legislative history and original intent of Congress in passing the Hatch-Waxman Act are not as important as the way courts have interpreted the Act. It is the courts' duty to interpret the law. The expanded interpretation evidenced by these cases must be applied going forward.

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[170] *Id.* at 1524.
[171] No. 95-Civ.-8833, 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001).
[172] *Id.* at *3 n.6.
[173] *Id.*
[174] 331 F.3d 860 (Fed. Cir. 2003), *rev'd*, 545 U.S. 193 (2005).
[175] *Id.* at 877 (Newman, J., dissenting).
[176] *Id.*

CONCLUSION

Hopefully the opportunity to consider the application of free testing under Section 271(e)(1) to in-house research tools arises in the near future. There are quality arguments both for and against the inclusion of the tools. Congress and the courts must take care to preserve the delicate balance between disclosure and exclusivity, which is involved in the application and issuance of every patent. Upsetting the balance may result in an erosion of patent protection for research tools that would halt innovation and further stray from the original principles of the American patent system.