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HATCH-WAXMAN'S SAFE-HARBOR PROVISION FOR PHARMACEUTICAL DEVELOPMENT: A FREE RIDE FOR PATENT INFRINGERS?

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ABSTRACT

The Safe-Harbor provision of the Hatch-Waxman Act allows generic drug manufacturers to use a patented invention during pre-market testing of generic drugs. However, the U.S. Court of Appeals for the Federal Circuit's recent interpretation of the Safe-Harbor provision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* created controversy when it extended the Safe-Harbor exemption to post-FDA approval. This extension was done in an unprecedented manner and would "allow almost all activity by pharmaceutical companies to constitute 'submission' and therefore justify a free license to trespass." The U.S. Supreme Court has yet to settle this matter, and courts are now faced with the unenviable task of adopting one of two irreconcilable but binding interpretations. This comment analyzes the conflict between the Federal Circuit judges' interpretations of the Safe-Harbor of the Hatch-Waxman Act. After analyzing the conflict, this comment offers guidelines that the Supreme Court should consider in limiting the Safe-Harbor provision in the Hatch-Waxman Act. Further, this comment proposes that courts should grant compulsory RAND licensing for analytical or diagnostic method patents if the patent is essential and required to meet the FDA's standards.

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I. INTRODUCTION

In this era of rapid, voluminous growth of biosimilar patent litigation, the Federal Circuit's recent and controversial decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*[1] gives brand pharmaceutical companies reason to worry. The court's broad interpretation of the Safe-Harbor provision of the Hatch-Waxman Act, which allows generic drug manufacturers to use a patented invention during pre-market testing of generic drugs,[2] would "allow almost all activity by pharmaceutical companies to constitute 'submission' and therefore justify a free license to trespass."[3]

It has become increasingly difficult to enforce biotechnological and name-brand pharmaceutical patents involved in drug discovery processes.[4] Congress enacted the Safe-Harbor to facilitate the development of generic drugs by granting the generic drug manufacturers the right to use patented drugs for the FDA regulatory approval process.[5] As a result, generic drugs would be immediately available to the public once a patent expired.[6]

Due to the broad language of the statute, however, courts have expanded the scope of the Safe-Harbor.[7] Prior to August 3, 2012, the Federal Circuit had limited the Safe-Harbor to use in conjunction with obtaining regulatory approval from the Food and Drug Administration ("FDA").[8] On August 3, 2012, the Federal Circuit held that the Safe-Harbor provision extends to post-FDA approval use as well.[9] As the Supreme

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[1] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1361 (Fed. Cir. 2012).

[2] 35 U.S.C. § 271(e)(1)(2006); H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984).

[3] *Momenta Pharms.*, 686 F.3d at 1367 (Rader, J., dissenting) (opining that the ultimate result of the court's decision in this case repeals the incentives and protections of the patent act).

[4] George Fox, Integra v. Merck*: Limiting the Scope of the S 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193, 214 (2004).

[5] *See* H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984).

[6] *See* 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, 122 (1999).

[7] *See* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 207 (2005) (stating that the court "decline[s] to read the 'reasonable relation' requirement so narrowly as to render § 271(e)(1)'s stated protection of activities leading to FDA approval for all drugs illusory"); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 661 (1990) (holding that the use of a patented invention to develop and submit information for "marketing approval of medical devices" under the Federal Food, Drug, and Cosmetic Act was not infringement).

[8] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1070 (Fed. Cir. 2011).

[9] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1357 (Fed. Cir. 2012).

Court recently passed on an opportunity to settle the matter,[10] courts are faced with the unenviable task of adopting one of two irreconcilable but binding interpretations.

This comment analyzes whether the Safe-Harbor provision should extend beyond the field of analytical drug testing after FDA approval. Part I introduces the history leading to the enactment of the Hatch-Waxman Act and the Safe-Harbor provision. Part II discusses the judicial interpretations, focusing on the *Momenta* case, and the present scope of the Safe-Harbor provision. It further examines the likely consequences and the policy concerns arising from the *Momenta* holding. Part III proposes how the Supreme Court should interpret the Safe-Harbor provision, and suggests amending 35 U.S.C. § 271(e)(1) to narrow the scope of the Safe-Harbor exemption.

I. BACKGROUND

A. The History of the Hatch-Waxman Act

The Hatch-Waxman Act gives a patent owner the exclusive right to exclude others from acts that infringe the patent.[11] Prior to this Act, that right was limited by the common law Experimental Use doctrine.[12] The Experimental Use doctrine requires a determination of the alleged infringer's intent to infringe the patent.[13] Consequently,

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[10] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 133 S. Ct. 2854, 2854 (2013).

[11] 35 U.S.C. § 154(a)(1) (2012). The statute provides:

> Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

Id.

[12] *See, e.g.*, Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 918–19 (2004) ("In the Federal Circuit's four precedential decisions in which an accused infringer asserted a common law-based experimental use defense, not once has the Federal Circuit applied the doctrine to absolve liability."). In 1813, Justice Story penned the *Whittemore v. Cutter* decision, in which he established the Experimental Use Doctrine. *Id.* at 927. In *Whittemore*, the defendant alleged that the court abused its discretion by giving a jury instruction that directed a finding of infringement if the jury found the defendant had made a machine with intent to profit. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (D. Mass. 1813). The court rejected his argument and found the instruction proper. *Id.* To infringe a patent, the infringer must make with the intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. *Id.* at 1121.

[13] *Whittemore*, 29 F. Cas. at 1121 ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."). Because Justice Story does not cite any authority for the rule, one commentator concluded:

courts have generally held that this exception applied when a minor activity that would otherwise constitute infringement of a patent was undertaken to verify results or for philosophical curiosity, rather than for actual commercial use.[14] Primarily, a number of subsequent courts applied the Experimental Use doctrine when the alleged infringer had not attempted to obtain any commercial gain or profit from the alleged activity.[15]

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[16] the Federal Circuit asserted the narrow limits of the Experimental Use doctrine within the pharmaceutical industry.[17] Bolar, the generic drug manufacturer, used Roche's patented drug six months before the patent was due to expire.[18] The purpose of the use was to perform necessary tests to obtain FDA approval of the drug's generic version.[19] Although the District Court for the Eastern District of New York held that Bolar's use of the patented drug was *de minimis* and experimental,[20] the Federal Circuit rejected Bolar's argument that the use of the patented drug was within the Experimental Use doctrine.[21] The court relied on 35 U.S.C. § 271(a) in determining that any use of a patented invention during the term of the patent constitutes infringement.[22]

Prior to the Hatch-Waxman Act, under the Food, Drug, and Cosmetic Act ("FDCA"), generic drug manufacturers were required to file a New Drug Application

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> [t]he only explanation for the experimental use exception which seems to make any sense is that Justice Story, after a brief reflection on the matter, simply felt that the plain language of the statute could not have really been intended to cover the case of a man sitting at home in his parlor or basement workshop and tinkering around with a piece of apparatus as a "philosophical experiment."

Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357, 367 (1957).

[14] Thomas F. Poche, *The Clinical Trial Exemption from Patent Infringement: Judicial Interpretation of Section 271(e)(1)*, 74 B.U.L. REV. 903, 909 (1994) (citing *Whittemore*, 29 F. Cas. at 1121).

[15] *See, e.g.,* Standard Measuring Mach. Co. v. Teague, 15 F. 390, 392–93 (D. Mass. 1883) (explaining a single machine made solely for display at an exhibition did not constitute infringement because the defendant had not attempted to sell the accused device); Kaz Mfg. Co. v. Chesebrough-Ponds, Inc., 317 F.2d 679, 681 (2d Cir. 1963) (stating assembly and use of a device shown as a short advertisement on a television commercial did not constitute infringement because the defendant was not seeking to market the accused device but was only using it for demonstration).

[16] Roche Prods., Inc. v. Bolar Pharm. Co., Inc. 733 F.2d 858, 867 (Fed. Cir. 1984).

[17] *Id.* at 863.

[18] *Id.* at 860.

[19] *Id.*

[20] Roche Prods., Inc. v. Bolar Pharm. Co., Inc. 572 F. Supp. 255, 258 (E.D.N.Y. 1983).

[21] *Roche Prods.*, 733 F.2d at 863. The court rejected Bolar's reliance on common law experimental use and held that "the experimental use exception to be truly narrow." *Id.* It also noted that "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* The court further explained that Bolar's use was performed with a "definite, cognizable, and not insubstantial commercial purpose[]." *Id.* Note that *Roche* is no longer precedential because of the subsequent enactment of the Hatch-Waxman Act. 35 U.S.C. § 271(e)(1) (2012).

[22] 35 U.S.C. § 271(a). "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." *Id.*

("NDA") to the FDA, which was similar to the name-brand pharmaceutical companies' filings.[23] Each application was supported by its own safety and efficacy studies to show its generic product was biologically equivalent to the brand drug.[24] This regulatory approval process frequently took two to three years.[25]

This state of affairs resulted in two unintended distortions of the standard patent term. The first distortion occurred because the lengthy FDA approval process prevented generic drug manufacturers from bringing a generic drug to the market upon the expiration of the patent, creating a *de facto* monopoly for the patentee of the name-brand drug even after expiration of the patent.[26] For this reason, generic drug manufacturers have argued that there should be a public policy exemption for bioequivalency testing before patents expire, to allow the public to enjoy the benefit of competition in the sale of patented drugs as soon as the patent expires.[27]

The second distortion applied adversely to the name-brand pharmaceutical companies. In addition to the lengthy FDA-approval process, the FDA-required testing was conducted only after a patent issues, which shortened the remaining effective exclusive term to as short as seven years.[28] The Federal Circuit refused to resolve these conflicting distortions between the FDCA, which ultimately increased the patent life due to the lengthy FDA approval process for generic drugs, and the Patent Act of 1952, which Congress intended to grant to patentees only a limited seventeen-year property right.[29] The Federal Circuit in *Roche* held that balancing the economic and social interests of name-brand pharmaceutical patentees, generic drug manufacturers, and the public is "legislative activity proper only for the Congress."[30]

B. Hatch-Waxman Act in 1984

In response to the *Roche* decision, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, to address the distortions in patent terms created by the FDA regulatory

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[23] Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

[24] 21 U.S.C. § 355(a) (2012). 21 U.S.C. § 355 requires an NDA to contain proof of efficacy (effectiveness) and safety of drugs, and the FDA must affirmatively approve the NDA. *Id.* The Federal Circuit noted that, according to a recent study, a pharmaceutical company may take on average from seven to ten years to satisfy the current regulatory requirements. *Roche Prods.*, 733 F.2d at 864.

[25] Fox, *supra* note 4, at 210–11.

[26] *Roche Prods*, 733 F.2d at 863–64.

[27] *Id.* at 864–65.

[28] *See* CHARLES C. EDWARDS, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY 79–80 (Nat'l Academy Press 1983) (citing statement of William M. Wardell to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives, Feb. 14, 1982, at 14).

[29] Daniel E. Troy, *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)*, U.S. FOOD AND DRUG ADMINISTRATION (August 1, 2003), http://www.fda.gov/newsevents/testimony/ucm115033.htm [hereinafter Troy, *Hatch-Waxman*]; 21 U.S.C. §§ 301–92.

[30] *Roche Prods.*, 733 F.2d at 864.

process.[31] By enacting the Hatch-Waxman Act, Congress endeavored to balance two conflicting policy objectives: (1) to encourage name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products; and (2) to accelerate the entry of generic drugs to the market to bring cheaper, generic copies of those name-brand drugs.[32]

Further, the Hatch-Waxman Act is divided into two titles.[33] The stated purpose of Title I is "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962."[34] Additionally, it abolished the lengthy NDA process for generic drug manufacturers and established an Abbreviated New Drug Application ("ANDA") process to expedite the FDA approval process for generic drugs.[35] As a result, the generic drug manufacturers are no longer required to repeat lengthy and costly tests for safety and efficacy determinations.[36] The ANDA process only applies if the generic drugs are used for the same medical conditions and composed of the same active ingredients as the patented, name-brand drugs.[37]

Consequently, generic drug manufacturers only need to satisfy the manufacturing and bioequivalence requirement of the ANDA process.[38] Additionally, the Hatch-Waxman Act provided a significant incentive to generic drug manufacturers to file the

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[31] Drug Price Competition and Patent Term Restoration Act of 1984, PUB. L. NO. 98-417, 98 Stat. 1585 (codified at scattered sections of 15, 21, 28, and 35 U.S.C.) [hereinafter Hatch-Waxman Act]; H.R. REP. NO. 98-857, pt. 1, at 17–18 (1984).

[32] Hatch-Waxman Act, *supra* note 31, at 1585.

[33] H.R. REP. NO. 98-857, pt. 1, at 16, 17 (1984).

[34] *Id.* at 14.

[35] *Id.* at 15. Prior to enactment of the Hatch-Waxman Act, an ANDA process already existed for obtaining FDA approval of generic drugs if their equivalent patented drugs were approved by the FDA before 1963. *Id.* at 16. The Hatch-Waxman Act extended the ANDA process to the approval of generic version of patented drugs approved by the FDA after 1962. *Id.*

[36] *Id.* 16.

[37] *See generally* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012). The court explained, "Those amendments allow a generic competitor to file an [ANDA] piggy-backing on the brand's NDA." *Id.* The court continued, "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.*

[38] Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 HARV. J. LAW & TECH. 281, 291 (2011). Once the ANDA is filed, the generic drug manufacturers must notify the patent holder claiming that either the patent is invalid or the patent will not be infringed by the manufacture, use, or sale of the generic drug manufacturers. *Id.* The patent owner must respond within forty-five days. *Id.* If he fails to respond to the notification, it is presumed that no issue of patent law arises and the FDA will proceed to the approval of the ANDA application. *Id.* However, most of the time, the patent owner files suit within forty-five days. *Id.* The Hatch-Waxman Act makes the filing of the ANDA "a constructive act of infringement, thus permitting the patent holder to sue for an injunction against the approval and marketing of the generic drug." *Id.* When this occurs, the Hatch-Waxman Act provides for "an automated stay of the ANDA process" which will remain in effect for thirty months or until the resolution of the lawsuit, whichever comes first. *Id.* at 292. If the lawsuit ends in favor of the ANDA filer, the filer has seventy-five days to begin to market its product or it must forfeit its 180-day exclusivity period. *Id.* According to Dolin, "[i]t is this provision that permits ANDA filers to settle suits with patentees while simultaneously keeping the benefits of the exclusivity period." *Id.* at 293; 21 U.S.C. § 355(j)(2)(B), (j)(5)(B)(iii) (2012) ("If the applicant made a certification described in subclause (IV) . . . the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is received, an action is brought for infringement of the patent.").

first ANDA, by granting the first filer a 180-day period of market exclusivity before subsequent generic drug manufacturers can enter the market.[39] The 180-day period begins to run when the first filer commercially markets the generic drug or a court declares the existing patent invalid.[40] Thus, Title I of the Hatch-Waxman Act successfully allows generic drug manufacturers to provide cheaper and alternative drugs for the public's benefit.[41]

C. The Safe-Harbor Provision

Title II of the Hatch-Waxman Act was proposed to mitigate distortions in patent terms created by the lengthy FDA regulatory process.[42] The stated purpose of Title II is "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval."[43] To counterbalance the benefit to generic drug manufacturers, name-brand pharmaceutical companies are eligible to extend a patent life period up to a maximum of five years.[44] This is intended to restore the time lost on a patent's life as result of the lengthy NDA process.[45]

In addition, Congress enacted the second section of Title II,[46] known as the Safe-Harbor provision, to enable the sale of generic drugs immediately after the patent expires.[47] For public policy reasons, it is important that Congress sought to ensure public access to beneficial new products at competitive market prices immediately after the expiration of the terms of relevant patents.[48] Thus, the Safe-Harbor provision provides a statutory exception to patent infringement liability.[49] It states that it is not an act of infringement "to make, use, offer to sell, or sell . . . a patented invention" for the sole purpose of developing and submitting information under a federal law that "regulates the manufacture, use, or sale of drugs."[50]

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[39] 21 U.S.C. § 355(j)(5)(B)(iv).

[40] *Id.*

[41] *See generally* Harold C. Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor*," 15 FED. CIR. B.J. 1, 21–22 (2005).

[42] *See* H.R. REP. NO. 98-857, pt. 1, at 15 (1984).

[43] *Id.*

[44] 35 U.S.C. §§ 156(c), 156(g)(6) (2012).

[45] *See id.*

[46] *See* H.R. REP. NO. 98-857, pt. 1, at 15 (1984).

[47] *Id.*

[48] *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) (construing § 271(e)(1) as the Court of Appeals decided that medical devices are included, "one must posit a good deal of legislative imprecision; but to construe it as petitioner would, one must posit that and an implausible substantive intent as well").

[49] 35 U.S.C. § 271(e)(1).

[50] *Id.* Section 202 of Title II of the Hatch-Waxman Act was codified as 35 U.S.C. § 271(e)(1), which states:

> [i]t 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 . . . 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.

Ultimately, the Safe-Harbor provision permits generic drug manufacturers to engage in otherwise infringing activities during the life of a patent, as long as the use is reasonably related to the submission of information under federal law regulating the sale of drugs.[51] Due to the broad language of this statute, a proper interpretation of the Safe-Harbor provision requires an understanding of the legislative history.[52]

The legislative history of the Hatch-Waxman Act suggests that the Safe-Harbor provision should be read very narrowly and strictly.[53] Commentators have described it as "limited to human drug products, and [not inclusive of] medical devices, animal drugs, food additives, color additives, or other related products."[54] Some Committee members raised concerns and proposed amendments to the Safe-Harbor provision, arguing that such provision restricts the exclusive right of the patent holder.[55] Congress rejected these amendments, however, and reasoned that the patent holder still retains the right to exclude others from the major commercial marketplace during the life of the patent.[56] Although Congressional opponents and proponents of the Safe-Harbor provision had different views concerning the patent rights, they shared the view that the provision should have a limited scope confined to the facts and circumstances presented in *Roche*.[57]

Thus, Congress unambiguously had a narrow view of the Safe-Harbor provision in which the "only activity" allowed under this section was a limited amount of bioequivalency testing undertaken by "generic manufacturers."[58] However, subsequent judicial interpretations have gradually expanded the scope of the Hatch-Waxman's Safe-Harbor exemption.

II. ANALYSIS

How broadly the Safe-Harbor provision should be read is a point of controversy in the legal community. Because of its broad language, courts have struggled to determine the scope of the infringement exemption created by the Safe-Harbor provision.[59] Consequently, courts are split as to how they should interpret the statute.

Id.

[51] *See* H.R. REP. NO. 98-857, pt. 1, at 45 (1984). The stated purpose of this provision 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." *Id.*; *see also* Brian Coggio & F. Dominic Cerrito, *The Safe Harbor Provision of the Hatch-Waxman Act: Present Scope, New Possibilities, and International Considerations*, 57 FOOD & DRUG L.J. 161, 161-62 (2002).

[52] *See generally* Fox, *supra* note 4, at 204–05.

[53] *See* H.R. REP. NO. 98-857, pt. 2, at 25–26 (1984).

[54] *See generally* 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, 308 (1985).

[55] *See* H.R. REP. NO. 98-857, pt. 2, at 29 (1984).

[56] *See generally* Fox, *supra* note 4, at 198.

[57] *See generally id.* at 199–200.

[58] *See* H.R. REP. NO. 98-857, pt. 2, at 8 (1984).

[59] *See generally* Coggio & Cerrito, *supra* note 51, at 162–63. Courts have generally agreed that the purpose of the Safe-Harbor is to provide exemption from a patent infringement suit where the testing of the patented invention is for (1) the purpose of securing regulatory approval from the FDA

Some judges argue that the provision should be read broadly, because it was intentionally written without restrictive words.[60] The Supreme Court has reasoned that if Congress intended to limit the exemption, then it would have clearly expressed that intent in the statute.[61] On the other hand, some judges have found that the Safe-Harbor provision was approved because it was "limited in time, quantity, and type."[62] Thus, they believe the provision should only apply to FDA's premarketing approval and would not apply to commercial sales.[63]

The legislature emphasized the narrowness of the exemption by stating that "a generic drug manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product *if* the purpose of those tests is *to submit an application to FDA for approval*."[64] It further stated that "the *only* activity which will be permitted by the bill is a *limited* amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent."[65] As a result, the court in *Scripps Clinic & Research*

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and (2) to prepare for commercial activity which will begin after a valid patent expires. *See generally* Fox, *supra* note 4, at 197–98.

[60] *See, e.g.,* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 672–73 (1990) (expanding the types of "patented inventions" under the Safe-Harbor exemption to include all inventions and not just those limited to drug-related invention, holding that the development of medical devices should be treated similarly to the development of drugs); Intermedics v. Ventritex Co., No. 92-1976, 1993 U.S. App. LEXIS 3620, at *16–17 (Fed. Cir. Feb. 22, 1993); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 2001 U.S. Dist. LEXIS 19361, at *26–28 (S.D.N.Y. 2001); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 207 (2005).

[61] *See, e.g.*, *Eli Lilly*, 496 U.S. at 667 ("If only the former patents were meant to be included, there were available such infinitely more clear and simply ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected.").

[62] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d. 1348, 1365 (Fed. Cir. 2012) (Rader, J., dissenting); *see also* Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (adopting the narrower interpretation of the Safe-Harbor provision by reading "solely" as modifying "reasonably related" so that the infringing party must demonstrate that it made and used the patented invention "solely" for the purpose of meeting FDA reporting requirement).

[63] *Momenta Pharms.*, 686 F.3d. 1348, 1364 (Rader, J., dissenting).

> The purpose of the foregoing provision is to permit a generic drug manufacturer to engage in the *limited experimental activities which are necessary to obtain FDA pre-marketing approval* before a patent expires so that actual competition between the generic drug and the original drug can begin immediately after the patent covering the original drug expires. Section 202 does not authorize any activity which would deprive the patent owner of the sale of a single tablet during the life of a valid patent. In fact, the *limited testing activity* required *to obtain FDA approval of a generic drug* would not normally result in the use of even a single generic tablet for its therapeutic purpose during the life of a valid patent.

Id. (quoting Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary, 98th Cong. 926 (1984)) (emphases adjusted); H.R. REP. NO. 98-857, pt. 1, at 45 (1984) (stating that the Safe-Harbor provision "does not permit the commercial sale of a patented drug by the party using the drug to develop such information, but it does permit the commercial sale of research quantities of active ingredients to such party").

[64] *Momenta Pharms.*, 686 F.3d at 1364 (emphasis in original).

[65] *Scripps Clinic*, 666 F. Supp. at 1396.

Foundation v. Genentech, Inc.[66] held that the Safe-Harbor exemption applies to those activities that are *solely* related to the development and submission of information to the FDA.[67]

A conflict between Federal Circuit judges' interpretations of the exemption led to contradictory decisions in the recent cases of *Classen Immunotherapies, Inc. v. Biogen IDEC*.[68] and *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals*, *Inc*.[69] Unfortunately, the Supreme Court recently denied a petition for writ of certiorari in both cases[70] and thus, missed the opportunity to resolve the conflicting decisions of the Federal Circuit. Consequently, courts are now faced with the unenviable task of adopting one of two irreconcilable but binding interpretations.

Although the Supreme Court denied cert in these cases now, the Court will eventually have to settle the Safe-Harbor exemption issue because the Federal Circuit judges have opposing views and interpretations of the Safe-Harbor provision in the Hatch-Waxman Act. Judge Moore, who dissented in *Classen*, wrote the *Momenta* decision. Judge Rader, who joined in the majority opinion in *Classen*, wrote a vigorous dissent in *Momenta*. In the *Momenta* decision, Judge Moore did not follow the precedent in *Classen*, thus yielding a contradictory result. Unless the Supreme Court sets clear guidelines as to how to interpret the Safe-Harbor provision, future decisions will depend solely on which judge gets one extra vote.

Further, *Classen* held that the Safe-Harbor provision does not apply to information that may be routinely reported to the FDA after marketing approval has been obtained.[71] The court reasoned that the provision sought to expedite development of information for regulatory approval of generic counterparts of patented products.[72] It relied heavily on the clear legislative history and the purported purposes of the Hatch-Waxman Act.[73] The opinion also stated that the Safe-Harbor only applies to pre-approval activities.[74] Consequently, the court held that the Safe-Harbor exemption is limited to the premarketing approval of generic drugs, and the infringing use after FDA market approval does not qualify as such an exemption.[75]

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[66] *Id.* at 1396.

[67] *Id.*

[68] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1070 (Fed. Cir. 2011) (holding that the Safe-Harbor provision should not extend beyond the pre-FDA premarketing approval of generic drugs).

[69] *Momenta Pharms.*, 686 F.3d at 1357 (extending the Safe-Harbor provision to the post-FDA approval). Although Amphastar was the first generic drug manufacturer to file an ANDA on the generic version of Lovenox (enoxaparin) to the FDA, Momenta received the FDA approval a year before Amphastar, and was the first to bring generic enoxaparin to the market. *Id.* at 1351. Lovenox is a drug that prevents blood clots. *Id.* at 1349. The generic enoxaparin is a low molecular weight of heparin, which is a naturally occurring molecule. *Id.* Heparin is a complex polysaccharide that have "considerable diversity in (1) the length of the polysaccharide chain and (2) in the component disaccharide units and the corresponding distribution of disaccharide unit sequences in the polysaccharide chains." *Id.* at 1349.

[70] GlaxoSmithKline v. Classen Immunotherapies, Inc., 133 S. Ct. 973, 973 (2013); Momenta Pharms. Inc. v. Amphastar Pharms. Inc., 133 S. Ct. 2854, 2854 (2013).

[71] *Classen*, 659 F.3d at 1070.

[72] *Id.*

[73] *Id.* at 1071.

[74] *Id.* at 1070.

[75] *Id.*

However, only a year after its decision in *Classen*, the Federal Circuit announced its seemingly contradictory decision in *Momenta*.[76] In that case, the FDA required an ANDA applicant for a generic drug, enoxaparin, to establish sameness because of the complicated scientific and regulatory issues attendant to approval of generic enoxaparin.[77] In order to satisfy this requirement, Momenta developed and patented a set of "manufacturing control processes" to confirm that each batch of its generic product contained a certain percentage of the unique sugars which correspond to the characteristic of enoxaparin.[78] Further, the FDA required generic drug manufacturers of enoxaparin to retain all records associated with a produced batch of drugs for authorized inspection by the FDA.[79]

Subsequent to the issuance of Momenta's analytical method patent, the FDA approved Amphastar's ANDA for generic enoxaparin.[80] Momenta sued Amphastar for infringement of its analytical method patent for manufacturing generic enoxaparin for commercial sale using the claimed methods.[81] Following *Classen*, the District Court of Massachusetts held that the Safe-Harbor exemption did not apply to Amphastar's post-FDA approval testing based primarily on the legislative history of the Safe-Harbor.[82]

The Federal Circuit reversed the district court's decision and held that Amphastar's action does fall within the scope of the Safe-Harbor exemption.[83] Contrary to the Supreme Court's holding in *Eli Lilly & Co. v. Medtronic, Inc.*,[84] the Federal Circuit found that the Safe-Harbor provision is unambiguous by omitting critical statutory language: "solely" and "submission."[85] It further stated that the

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[76] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1361 (Fed. Cir. 2012).

[77] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 882 F. Supp. 2d 184, 188 (D. Mass. 2011). Because Enoxaparin is produced by breaking the complex heparin polysaccharide into smaller pieces, called oligosaccharides, the enoxaparin is made up of a mixed variety of oligosaccharides units corresponding to the diversity in the original mix of heparin molecules. *Id.* at 187. The brand-name pharmaceutical company that manufactured Lovenox petitioned to the FDA that its generic version required careful analysis. *Id.* at 188. In response, the FDA imposed five criteria to ensure its "sameness:" (1) the physical and chemical characteristics of enoxaparin, (2) the nature of the source material and the method used to break up the polysaccharide chains into smaller fragments, (3) the nature and arrangement of components that constitute enoxaparin, (4) certain laboratory measurements of anticoagulant activity, and (5) certain aspects of the drug's effect in humans. *Id.*

[78] *Id.* at 188.

[79] *Momenta Pharms.*, 686 F.3d at 1357 (requiring records to be available for at least one year after the expiration date of the batch).

[80] *Id.* at 1351.

[81] *Id.* at 1351, 1352.

[82] *Momenta Pharms.*, 882 F. Supp. 2d at 196 (emphasizing that the only activity that is permitted by the Safe-Harbor provision is a limited amount of testing for purposes of submitting data for FDA approval) (citing Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1071 (Fed. Cir. 2011)).

[83] *Momenta Pharms.*, 686 F.3d at 1361.

[84] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 661 (1990).

[85] *Momenta Pharms.*, 686 F.3d at 1362 (Rader, J., dissenting); *Eli Lilly*, 496 U.S. at 669 (1990) (finding that the statute can be ambiguous and "not plainly comprehensible"). The court disagreed with the dissenting opinion that the words "solely" and "submitted" limit the statute to pre-approval activities. *Id.* at 1359–60. *But see id.* at 1367 (Rader, J., dissenting) (emphasizing that omitting the word "solely" is not proper reading of the Safe-Harbor provision and that Amphastar's activity is not within the statute because its use was not solely for developing and submitting information to the FDA).

FDA's requirement to maintain records is "reasonably related" to submitting to the FDA.[86]

Additionally, the court tried to distinguish *Momenta* from *Classen* by emphasizing that: (1) Amphastar's submission to the FDA in this case was not "routine" and (2) the FDA mandated the performance of the patented studies.[87] The Court stated that this analysis "is not groundbreaking" because the Supreme Court came to essentially the same conclusion in *Eli Lilly*.[88]

However, as Judge Rader in the dissent noted, there is nothing in *Eli Lilly* that suggests the exemption goes beyond the premarketing approval of generic counterparts before patent expiration.[89] In *Classen* and in the dissent in *Momenta*, he emphasized that the Safe-Harbor exemption was only intended for limited "experimental use" for purposes of submitting data to the FDA for approval.[90] Judge Rader believed that the mere fact that the activities were "mandated by the FDA" could not justify Amphastar's infringing use.[91] Momenta spent time, money, and effort to invent the first and best method to satisfy the FDA requirement.[92] Because Momenta's method was so successful, the FDA adopted that method as a standard.[93] That does not mean, however, that the FDA intended for every other generic drug manufacturer to freely use Momenta's patented method without violating Momenta's exclusive right.[94] Amphastar was free to invent its own method, but instead chose to trespass.[95]

Further, it is also "questionable whether Momenta's patented analytical method . . . even qualifies as a 'patented invention' that is subject to this 'safe harbor' provision."[96] Unlike the prior cases, *Momenta* did not involve the use of a brand-name drug patent to obtain FDA approval. It involved the use of an analytical method patent for biosimilarity, which is required after FDA approval in order to maintain the approval.

The Supreme Court held in *Eli Lilly* that "patented inventions" extend to medical devices reasonably related to the development and submission of information to the

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[86] *Momenta Pharms.*, 686 F.3d at 1357.

[87] *Id.* at 1353.

[88] *Id.* at 1355. However, nothing in either Eli Lilly or Merck suggests that the Supreme Court intended the "safe harbor" to reach post-FDA approval activity. *See generally* Eric W. Guttag, *Momenta Pharmaceuticals: The Hatch-Waxman "Safe Harbor" Widens to Include Post-FDA Approval Activity*, IPWATCHDOG (Aug. 7, 2012, 10:27 AM), http://www.ipwatchdog.com/2012/08/07/momenta-pharmaceuticals-the-hatch-waxman-safe-harbor-widens-to-include-post-fda-approval-activity/id=27191/ [hereinafter Guttag, *Momenta Pharmaceuticals*]

[89] *Momenta Pharms.*, 686 F.3d at 1368 (Rader, J., dissenting).

[90] *Id.* at 1364–65.

[91] *Id.* at 1369.

[92] *Id.* at 1362. Some scholars doubt "whether Momenta's patented analytical method . . . even qualifies as a 'patented invention' that is subject to this 'safe harbor' provision." Guttag, *Momenta Pharmaceuticals*, *supra* note 88.

[93] *Momenta Pharms.*, 686 F.3d at 1370 (Rader, J., dissenting).

[94] *Id.* at 1369. Momenta's decision is already criticized by scholars that the court made "its own independent interpretation" of the Safe-Harbor provision. *See generally* Kevin E. Noonan, *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmacueticals, Inc. (Fed. Cir. 2012)*, PATENT DOCS BIOTECH & PHARMA PATENT LAW & NEWS BLOG (Aug. 9, 2012, 11:59 PM), http://www.patentdocs.org/2012/08/momenta-pharmaceuticals-inc-v-amphastar-pharmaceuticals-inc-fed-cir-2012.html.

[95] *Momenta Pharms.*, 686 F.3d at 1369 (Rader, J., dissenting).

[96] Guttag, *Momenta Pharmaceuticals*, *supra* note 88.

FDA for the purpose of obtaining marketing approval for a medical device.[97] The Court reasoned that if Congress intended to limit the exemption to only drug patents, then they would have clearly expressed that intent in the statute.[98] However, *Momenta* is distinguishable from *Eli Lilly* because the use was not for obtaining FDA approval. Thus, analytical method patents may not be within the definition of a "patented invention" which the Safe-Harbor provision intends to exempt.

Judge Rader stated that the court "rewrote" the law, contrary to legislative history and precedent, to allow Amphastar's infringement "throughout the entire life of Momenta's patent and for the purpose of obtaining profits on commercial sales of a product that competes with the patentee."[99] He pointed out that this new interpretation would "allow almost all activity by pharmaceutical companies to constitute 'submission' and therefore justify a free license to trespass."[100] Consequently, manufacturing method patents will become worthless because no incentive remains to invest in developing a better test.[101] Judge Rader highlights that this approach ultimately violates the essence of the patent law and future research incentives in this field.[102]

On the other hand, some scholars have shown concern that patenting the "analytical process for demonstrating biosimilarity" raises a problem, especially when "there are no practical, alternative methods available for demonstrating biosimiliarity."[103] Thus, unless the Safe-Harbor provision applies, the owner of the analytical process patent can potentially prevent competitors from bringing a biosimilar to market because competitors could not demonstrate biosimilarity required by the FDA without infringing the patent.[104]

At the same time, it is strongly suggested that the use of the patented analytical method for the purpose of manufacturing a product to sell on the market falls outside of the protected scope of the Safe-Harbor provision.[105] Clear guideline is required, where courts agree on the scope of the Safe-Harbor provision to avoid such conflicting results between the courts and judges.

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[97] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 661 (1990) (holding that the Safe-Harbor provision is not limited to drugs only).

[98] *Id.* at 667. The court pointed out, "If only the former patents were meant to be included, there were available such infinitely more clear and simpl[e] ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected." *Id.*

[99] *Momenta Pharms.*, 686 F.3d at 1366 (Rader, J., dissenting) (emphases omitted). The dissent strongly argued that this unwarranted expansion of the law circumvents the purpose of the patent law. *Id.* In addition, it completely ignores the legislative history (which is strongly supported in binding precedents), which strongly suggest that the intention of the Safe-Harbor provision applied only in limited situations, namely pre-approval experiments to obtain FDA approval. *Id.* (citing Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1070–71 (Fed. Cir. 2011)).

[100] *Momenta Pharms.*, 686 F.3d at 1367 (Rader, J., dissenting). The ultimate result of the court's decision in this case repeals the incentives and protections of the patent act. *Id.*

[101] *Id.* at 1362.

[102] *Id.* at 1362, 1375–76.

[103] Chris Holman, Momenta v. Amphastar*: A Divided Federal Circuit Panel Addresses Scope of Hatch-Waxman Safe Harbor for Post-Approval Activities*, HOLMAN'S BIOTECH IP BLOG (Oct. 4, 2012, 12:49 PM), http://holmansbiotechipblog.blogspot.ca/2012/10/momenta-v-amphastara-divided-federal.html.

[104] *Momenta Pharms.*, 686 F.3d at 1369–70, 1375–76 (Rader, J., dissenting).

[105] *See* Guttag, *Momenta Pharmaceuticals*, *supra* note 88.

III. PROPOSAL

This section proposes that (1) the Safe-Harbor provision in the Hatch-Waxman Act should not extend beyond the pre-FDA premarketing approval of generic drugs and (2) the Court should impose compulsory "reasonable and non-discriminatory terms" ("RAND") licenses if the patentee intended to commercialize its patent or if there is no other alternative. Every decision examining the statute has appreciated that the Safe-Harbor provision is directed to premarketing approval of generic counterparts before a patent expires.[106] Thus, *Momenta* extended the Safe-Harbor provision beyond its statutory language and was inconsistent with the legislative intent and judicial interpretation as to when the provision applies.[107]

A. Limited to pre-FDA approval

The Safe-Harbor provision was enacted, intended, and judicially interpreted to apply to limited activities that are conducted to obtain pre-FDA marketing approval of generic counterparts of patented inventions.[108] Extending it to the post-FDA approval creates a direct conflict with the prior judicial interpretation in *Classen*.[109] The Federal Circuit explicitly held that Classen's method patents did not fall under the Safe-Harbor exemption because the exemption does not include such activities targeted at gaining market approval.[110] It was noted that the provision does not extend to the information that may be routinely reported to the FDA after marketing approval has been obtained.[111]

Additionally, courts have considered and should continue to consider clear legislative intent while interpreting the Safe-Harbor provision.[112] The Safe-Harbor provision was provided in order to expedite development of information for regulatory approval of generic counterparts of patented products.[113] Further, it is clearly stated in the House Report that the provision exempts generic drug manufacturers from patent infringement if the use was "to import or to test a patented drug in *preparation* for *seeking FDA approval*, if marketing of the drug would occur *after* expiration of the patent."[114] The Report is replete with statements that the legislation concerns premarketing approval of generic drugs and emphasizes that "[t]he information which can be developed under this provision is the type which is required to obtain approval of the drug."[115] There is nothing in the Report that suggests that Congress intended to expand the Safe-Harbor provision beyond the pre-FDA approval.

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[106] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1071–72 (Fed. Cir. 2011).

[107] *See* H.R. REP. NO. 98-857, pt. 2, at 8–9 (1984); *Momenta Pharms.*, 686 F.3d at 1371-72 (Rader, J., dissenting).

[108] *See* H.R. REP. NO. 98-857, pt. 2, at 8–9 (1984).

[109] *Classen*, 659 F.3d at 1070.

[110] *Id.* (involving analytical method for studies to evaluate the association between the timing of child vaccination and the development of immune-mediated disorders).

[111] *Id.*

[112] *Id.* at 1071.

[113] Troy, *Hatch-Waxman*, *supra* note 29; Roche Prods., Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858, 864 (Fed. Cir. 1984); 21 U.S.C. §§ 301–92 (2012).

[114] *Classen*, 659 F.3d at 1071 (citing H.R. REP. NO. 98-857, pt. 1, at 15 (1984)) (emphasis added).

[115] *Id.*

Further, Congress certainly did not intend to apply the Safe-Harbor exemption to commercial sales. The purpose of the provision was to respond to two unintended distortions of the seventeen-year patent term, which resulted from the long process of premarket regulatory FDA approval.[116] So the Safe-Harbor provision exempts generic drug manufacturers, allowing them to use the patented drug before the patent expires, for the sole purpose of obtaining the regulatory approval for their generic counterparts. This allows generic drug manufacturers to enter into the market immediately after patent expiration.[117] Thus, the Safe-Harbor was never meant to be applied to commercial sales during the life of the patent.[118]

However, there has been a full-blown scholarly and judiciary debate as to how statutes should be generally read: textualism versus intentionalism.[119] It is important to read the statute on its face, and according to Justice Scalia, the legislative intent is irrelevant if the text is plain and unambiguous.[120] From this view, it logically follows that when the statute language is ambiguous, courts should consider the legislative intent to interpret the statute.[121] The ambiguity can be inferred from the existing dispute between judges as to how the statute should be read. Contrary to the majority's opinion in *Momenta*, it stands to reason that the Safe-Harbor provision is ambiguous because courts have been going back and forth about how far the provision extends.

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[116] H.R. REP. NO. 98-857, pt. 1, at 15 (1984).

[117] *Id.* There has been extensive precedent that recites the purpose of the Safe-Harbor provision and there has been no dispute as to what that is, which is to facilitate market entry upon patent expiration. *See, e.g.,* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1358 (Fed. Cir. 2003) (stating that the Safe-Harbor provision enabled "generic manufacturers to test and seek approval to market during the patent term"); Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008) (examining for purposes of the exemption whether the infringer is "seeking FDA approval [for a product] in order to enter the market to compete with patentees").

[118] Guttag, *Momenta Pharmaceuticals*, *supra* note 88.

[119] Frank H. Easterbrook, *The Role of Original Intent in Statutory Construction*, 11 HARV. J.L. & PUB. POL'Y 59, 65 (1988). Textualism, a formalist theory of statutory interpretation, suggests that the statute should be interpreted by "look[ing] at the statutory structure and hear[ing] the words as they would sound in the mind of a skilled, objectively reasonable user of words." *Id.* Thus, the textualist does not give weight to legislative history materials when attempting to ascertain the meaning of a text. *Id.* at 60–61. Textualist judges have contended that courts should not treat committee reports as authoritative evidence of legislative intent. *Id.* at 60. These judges reasoned that (1) a 535-member legislature has no "genuine" collective intent concerning the proper resolution of statutory ambiguity and even if it did it would be hard to prove that the "intent" was of Congress as a whole, (2) giving weight to legislative history offends the constitutionally mandated process of bicameralism and presentment. John F. Manning, *Textualism as a Nondelegation Doctrine*, 97 COLUM. L. REV. 673, 675 (1997).

[120] *See* Brogan v. United States, 522 U.S. 398, 406–08 (1998).

[121] *See e.g.,* Muscarello v. United States, 524 U.S. 125, 138–39 (1998) ("The simple existence of some statutory ambiguity . . . is not sufficient to warrant application of [the rule of lenity], for most statutes are ambiguous to some degree . . . . To invoke the rule, we must conclude that there is a 'grievous ambiguity or uncertainty' in the statute."); United States v. R.L.C., 503 U.S. 291, 311 (1992) (Thomas, J., concurring-in-part and concurring-in-the-judgment) (noting that "the rule [of lenity] operates only 'at the end of the process' of construction, if ambiguity remains 'even after a court has seize[d] every thing from which aid can be derived'"). Under law as legislative intent, where both the text of a statute and the enacting Congress' intent are clear but contradict one another, the clear intent of the enacting Congress prevails. *See generally* William N. Eskridge, Jr., *The New Textualism*, 37 UCLA L. REV. 621, 646–50 (1990).

Therefore, limiting the scope of the exemption for the purpose of obtaining the pre-FDA marketing approval would protect the primary purpose and intent of the Safe-Harbor provision.

B. Compulsory "Reasonable and Non-Discriminatory Terms" ("RAND") Licensing

The *Momenta* decision raised some concerns and fears among analytical method patent holders. If the Supreme Court decides to uphold *Momenta*, it will discourage drug manufacturers from disclosing their new analytical method. One of the reasons why the patent law grants an exclusive right to exclude others from acts that infringe the patent is to encourage new innovations that benefit the public.[122] At the same time, as a matter of public policy it is important to introduce generic counterparts of beneficial drugs as soon as possible, so that they are available to the public for a reasonable and affordable price. Thus, it is important to interpret the Safe-Harbor provision in a way that balances the need for innovation against public health concerns.

The author submits that a system of compulsory "reasonable and non-discriminatory" ("RAND") licensing would provide courts with a practical method for achieving that balance. Reasonable and non-discriminatory terms, also known as "fair, reasonable, and non-discriminatory terms" ("FRAND") in Europe, are a licensing obligation that is often required by standards organizations.[123] The standard-setting organizations ("SSOs") set common standards for a particular industry in order to prevent members from monopolizing the market by engaging in patent licensing abuse: refusing to license or charging excessively high royalty rates.[124] Therefore, companies with patents that have been selected for a standard are obligated to RAND commitment because its patent is "essential" and thus "required" to meet the standard.[125]

Under such a system, courts would determine whether analytical method patents were "essential" and "required" to meet the FDA's standards. For example, compulsory RAND licensing is applicable in *Momenta* where the use of patent was "essential" to meet the FDA's standards. If there is absolutely no alternative to design around the patent to achieve the similar result, the compulsory RAND licensing should be granted in order to prevent an unreasonable monopoly. For example, if the generic drug manufacture has a patented analytical process, it can potentially prevent other generic companies to enter into the market, thus creating a monopoly of the generic drug after the brand-named drug patent expires. Preventing the generic drugs from entering freely into the market after the brand-named patent expires is contrary to what the Safe-Harbor provision intended.[126] Thus, courts have to balance the patentees' exclusive rights with the importance of availability of the generic drugs for the public.

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[122] AMY L. LANDERS, UNDERSTANDING PATENT LAW 10–14 (1st ed., LexisNexis 2008).

[123] Anne Layne-Farrar et al., *Pricing Patents for Licensing in Standard-Setting Organizations: Making Sense of FRAND Commitments*, 74 ANTITRUST L.J. 671, 671 (2007).

[124] *Id.* at 672.

[125] *Id.*

[126] *See* Wegner, *supra* note 41, at 2.

The Safe-Harbor exemption was only intended for limited "experimental use" for purposes of submitting data to the FDA for approval.[127] The fact that the FDA mandated the activities cannot justify the infringing use.[128] If such activities are required after FDA approval, they should be supported by proper patent licensing. Thus, a compulsory license would allow a patentee to still enjoy a commercial benefit from its analytical or diagnostic method patent, and at the same time would fulfill the benefit of providing cheaper alternative generic drugs to the public at a faster rate.

IV. CONCLUSION

Extending the Safe-Harbor exemption in the Hatch-Waxman Act to post-FDA approval was done in an unprecedented manner, and contradicted the clear intent of the legislature. Consequently, manufacturing analytical or diagnostic method patents will have less value because there is no incentive to invest in developing a better test. The Supreme Court should consider the clear legislative intent and prior judicial decisions, and limit the Safe-Harbor provision in the Hatch-Waxman Act to only apply to obtaining pre-FDA marketing approval. Furthermore, the court should grant compulsory RAND licensing for analytical or diagnostic method patents if the patent is essential and required to meet the FDA's standards.

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[127] Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1367, 1375–76 (Rader, J., dissenting).

[128] *Id.* at 1369.