

5-1-2014

The Future of Patent Protection for Post-FDA-Approved Generics: A Look at the Federal Circuit's Incongruous Interpretations of 35 U.S.C. § 271(e)(1)'s "Safe Harbor" Provision

Alexandra Bollman Robertson

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship

Recommended Citation

Robertson, Alexandra Bollman, "The Future of Patent Protection for Post-FDA-Approved Generics: A Look at the Federal Circuit's Incongruous Interpretations of 35 U.S.C. § 271(e)(1)'s "Safe Harbor" Provision" (2014). *Law School Student Scholarship*. 555. https://scholarship.shu.edu/student_scholarship/555

The Future of Patent Protection for Post-FDA-Approved Generics: A Look at the Federal Circuit's Incongruous Interpretations of 35 U.S.C. § 271(e)(1)'s "Safe Harbor" Provision

Alexandra B. Robertson

I. INTRODUCTION

Two recent Federal Circuit decisions, *Classen Immunotherapies, Inc. v. Biogen, Idec*.¹ and *Momenta Pharmaceuticals, Inc. v. Amphastar*² have created an intra-circuit split regarding the scope of the Hatch-Waxman Act's "safe harbor" provision. The safe harbor protects generic pharmaceutical manufacturers from patent infringement claims by the brand-name pharmaceutical patent holder if the patented techniques are used for required submissions to the Food and Drug Administration ("FDA"), usually to obtain FDA approval. In the past, the issue with interpreting the scope of the safe harbor provision has been exclusively related to pre-market approval activities. These two cases address whether the safe harbor extends to activities *after* the drug has been approved. The panels deciding the two cases used different reasoning and ultimately came to two different conclusions; *Classen* uses the legislative history of the statute to interpret the scope of the safe harbor provision to exclude post-FDA-approval methods, while *Momenta* uses only the statutory text to interpret the statute to conclude that the scope of the safe harbor does include post-FDA-approval methods. These conflicting decisions have created uncertainty in the pharmaceutical industry and the issue needs to be resolved.

¹ *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011)

² *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012)

This Comment will discuss the potential negative impact that the uncertainty of the safe harbor’s scope will have on the pharmaceutical industry. Part II of this Comment will detail the background of the Hatch-Waxman safe harbor provision and how it influences the seemingly conflicting outcomes in *Classen* and *Momenta*. Part III will then address the implications these decisions will have on the future of generic drugs and the uncertainty that they create in the industry, and it will also suggest possible long-term and temporary solutions to this uncertainty. Ultimately, this Comment will suggest that the best way to define the scope of the safe harbor provision is to have the legislature address the issue through statutory amendment to clarify its limits and specifically state whether it applies to post-approval activities.

II. BACKGROUND

A. *The Drug Approval Process and Patent Implications*

The Federal Food, Drug, and Cosmetic Act (FDCA) regulates the manufacture, use, and sale of drugs.³ For a drug to enter the market, the FDCA requires that Food and Drug Administration (FDA) approve it by determining that it is safe and effective.⁴ For a pharmaceutical manufacturer to obtain this approval, it must submit a New Drug Application (“NDA”) to the FDA.⁵ This process requires multiple stages and usually takes many years to complete. During the first stage, the preclinical stage, pharmaceutical sponsor tests the toxicology of the drug by performing synthesis and purification, as well as some limited testing on animals.⁶ This stage can take up to six or seven years.⁷ After the completion of the drug’s preclinical testing, the manufacturer moves ahead to the clinical stage, which requires an

³ 21 U.S.C. 331, 355(a).

⁴ Id.

⁵ 21 USCA §355.

⁶ Id.

⁷ Id.

Investigative New Drug Application (“IND”), and three clinical phases.⁸ Phase I tests the safety of the drug by conducting clinical trials on healthy individuals; Phase II tests the safety, dosing, and efficacy through administering the drug to volunteers in the target population; and Phase III tests the safety, efficacy, and side effects of the drug.⁹ This stage is incredibly lengthy and spans between 6 and 11 years. Once that is completed, the manufacturer submits the NDA.¹⁰ The NDA explains the results of the clinical trials and sets forth the ingredients of the new drug, how it is manufactured, and how it works.¹¹ The FDA evaluates the drug safety, effectiveness, and labeling to determine whether it will be approved. Once the drug has obtained approval, it can be marketed with FDA regulated labeling.¹² The entirety of this FDA approval process can take anywhere from eleven to fourteen years.¹³

The lengthy time period required for FDA approval creates implications for both brand-name pharmaceutical manufacturers and generic manufacturers, and this is what the Hatch-Waxman Act sought to fix. Before Hatch-Waxman, the time necessary to obtain FDA approval consumed a large portion of the patent life of the brand-name drug, while the extent of time and money that a manufacturer had to invest to obtain approval was a huge disincentive to generic manufacturers.¹⁴ While the brand-name manufacturer holds the patent for the drug, generic companies are prohibited from selling the generic version on the market. This gives the brand-name drug company patent exclusivity of the drug for the life of the patent. Brand-name manufacturers lost some of the exclusivity benefits from the patent because the process required

⁸ Id.

⁹ Id.

¹⁰ Id.

¹¹ 21 CFR §314.

¹² Id.

¹³ U.S. Food and Drug Administration, <http://www.fda.org> (last visited Jan. 21, 2013)

¹⁴ Karbalai, Hasneen, *THE HATCH-WAXMAN (IM)BALANCING. ACT*, Harvard LEDA, 28 (2003).

the manufacturers to conduct lengthy clinical trials and await regulatory review before being able to place the drug on the market. This long process cut significantly into the limited term of the patent, and the patentee drug manufacturers “were unable to profit from their invention’s market exclusivity...limiting the economic advantage the patentees could derive from their temporary monopoly.”¹⁵ On the other end, there was little incentive for manufacturers to develop generic drugs.¹⁶ This lengthy FDA approval process created economic disadvantages for both the brand-name and generic manufacturers, highlighting the intersection between patent law and FDA regulation in this context.

Pharmaceutical manufacturers regularly seek patents for both their new and generic drug products. A patent gives the holder the “right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent.”¹⁷ This gives pharmaceutical companies incentive to invest in researching and developing new products. 35 U.S.C. 271(a) states that “whoever without authority makes, uses, offers to sell, or sells any patented invention during the term of the patent therefore, infringes the patent.”¹⁸ However, the Drug Price Competition on Patent Term Restoration Act of 1984, or 35 U.S.C. § 271, creates an exemption to this rule of infringement. The Act was enacted to amend the FDCA to address “the need for innovative new pharmaceuticals and the availability of less expensive generic drugs.”¹⁹ The act facilitates generic entry in the pharmaceutical market by making it easier for manufacturers to obtain FDA approval in a shorter period of time.²⁰ Prior to the Hatch-Waxman Act, the generic market was neither prevalent nor profitable. The generic drug company was

¹⁵ Id.

¹⁶ Id.

¹⁷ 35 U.S.C. 154.

¹⁸ 35 U.S.C. 271(a)

¹⁹ Schacht, Wendy H. & John R. Thomas, The “Hatch-Waxman” Act: Select Patent-Related Issues; Congressional Research Service (2002).

²⁰ Id.

required to submit an NDA with results of studies conducted to show the safety and effectiveness of the drug, even though the brand-name drug manufacturer already submitted safety and effectiveness studies.²¹ The extensive time and costs required for generic drug manufacturers to gain FDA approval made it unlikely that the manufacturer would not recover its investment. This was a huge disincentive for pharmaceutical manufacturers to invest in developing generic drugs.²²

The Hatch-Waxman Act was a response to the Supreme Court's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which prevented competitors from performing tests required for FDA approval using patented methods until those patents expired.²³ This result prevented generic manufacturers from beginning testing on the drug until the brand-name manufacturer's patent expired, which "resulted in the generic not being able to obtain FDA approval until about two years following the expiration of the brand innovator's patent."²⁴ Congress enacted the Hatch-Waxman to overrule *Roche*.²⁵ Title I of 35 U.S.C. § 271 sets out the procedure for the Abbreviated New Drug Applications ("ANDA"). This abbreviated procedure allows the generic to take advantage of the brand-name manufacturer's lengthy clinical research procedures. This speeds up the approval process for generic drugs, allowing them to enter the market much faster than if they had to go through the clinical research process that new drugs must complete, because they are now able to enter the market as soon as the patent expires.²⁶

²¹ Behrendt, Kristen E. THE HATCH-WAXMAN ACT: BALANCING COMPETING INTERESTS OR SURVIVAL OF THE FITTEST?, 57 Food & Drug L.J. 247 (2002).

²² Id. at 249.

²³ 733 F. 2d 858, 863 (Fed. Cir. 1984).

²⁴ Behrendt, Kristen E. THE HATCH-WAXMAN ACT: BALANCING COMPETING INTERESTS OR SURVIVAL OF THE FITTEST?, 57 Food & Drug L.J. 247 (2002).

²⁵ Fox, Allan M. & Bennet, Alan R., The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984, Food and Drug Law Institute, Inc. (1987).

²⁶ Allan M. Fox & Allan R. Bennet, The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984 (FDLI 1987).

Section 505(j) of the Food, Drug, and Cosmetics Act (“FDCA”) addresses the abbreviated process for FDA approval of generic bioequivalent drugs.²⁷ This provision allows manufacturers to file an ANDA, which rely on the original manufacturer’s safety and efficacy test results. The provisions of the ADNA do not require the generic manufacturer to submit its own safety and effectiveness studies. Instead, the manufacturer must submit information showing that the generic has the same active ingredients, dosage form, route of administration, and strength as the pioneer drug that the FDA has already approved.²⁸ The ANDA also requires the generic manufacturer to show that the generic drug is bioequivalent to the approved drug.²⁹ If a generic manufacturer can show bioequivalence between the generic drug and the pioneer drug, the FDA can approve the drug without the proof of safety or efficacy required for NDAs.³⁰ A generic drug is bioequivalent if it contains the same active ingredient as the original.³¹ Under the ANDA procedure, a drug is “bioequivalent” if

the rate and extent of absorption of the drug do not show significant difference from the rate and extent of absorption of the listed drug... or the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug... and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.³²

Because an ANDA requires bioequivalency requirement rather than safety and efficacy tests that the NDA requires, the generic is able to receive FDA approval much faster. The act attempts to balance the competing interests discussed above by extending the length of the patent term for brand-name manufacturers to restore some of the term that was lost due to clinical testing, while

²⁷ Federal Food, Drug, and Cosmetic Act §505(j).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ 21 USCA §355.

³² 25 Am. Jur. 2d Drugs and Controlled Substances §121.

allowing generic manufacturers to obtain FDA approval during the patent period (without being subject to infringement) and enter the market as soon as the patent expires.³³

The safe harbor provision in the Hatch-Waxman Act provides that “[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.”³⁴ The language of the statute leaves room for ambiguity and interpretation of certain terms by the courts. “The terms in the statutory language differ in certain respects from those in other provisions of the Act... [s]everal words and phrases ... raised several important questions that were left to the courts to determine.”³⁵ Specifically, the terms “solely,” “reasonably related,” and “development and submission of information” have caused courts to contemplate how the statute should be interpreted.

The legislative history of the Act gives some insight into the intended meaning of the statutory language. The legislature strove to “restore patent terms to pharmaceutical inventions in order to offset the lengthy waiting period prior to receiving FDA pre-market approval to sell a new drug” and “permit generic companies to use the patented products in preparing their applications for similar regulatory approval before the patent terms expire so that brand companies cannot enjoy a longer monopoly than allowed by the patent statute.”³⁶ Excerpts from the Congressional record indicate that the limited purpose of the safe harbor provision was to facilitate the generic drug application process to the FDA for approval. During this process, the generic manufacturer must submit data to the FDA to establish bioequivalence, and “in order to

³³ Id.

³⁴ 35 U.S.C. § 271(e)(1)

³⁵ Karbalai, Hasneen, THE HATCH-WAXMAN (IM)BALANCING ACT, Harvard LEDA, 28 (2003).

³⁶ Wang, Chenwei, IN SEARCH OF THE BOUNDARY OF THE SAFE HARBOR, 19 Fed. Cir. B.J. 617 (2010).

complete this application the generic manufacturer must conduct certain drug tests. In order to complete this type of testing, section 202 of the bill creates general exception to the rules of patent infringement. Thus, a generic 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 for FDA approval.*³⁷

The legislative history suggests that the safe harbor is intended to allow for activities only in preparation for commercial activity. Rep. Kastenmeier stated, in the House Floor Debate, that “[t]he purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to *prepare* for commercial activity which will begin after a valid patent expires, is not patent infringement.”³⁸ The Legislature intended only minimal interference with a patent holder’s rights through application of this provision. As stated in the House Report Part 2, “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 ... thus, the nature of the interference with the rights of the patent holder is not substantial.”³⁹ The Legislature had several concerns regarding the safe harbor provision during the process of enacting it, such as “[t]aking property rights away from people and away from companies” and “compromis[ing] the rights of present patent holders by permitting their adverse use of that particular product by potential competitors prior to the time that the patent expires.”⁴⁰ There

³⁷ Remarks of Rep. Kastenmeier, House Floor Debate, Cong. Rec. of August 8, 1984, at H8708 (emphasis added).

³⁸ *Id.*

³⁹ House Report Part 2, at pages 8-9.

⁴⁰ Remarks of Rep. DeWine, House Floor Debate, Cong. Rec. of August 8, 1984, at H8710; Remarks of Rep. Moorhead, House Floor Debate, Cong. Rec. of August 8, 1984, at H8710.

were also concerns that this leniency on patent infringement would contradict the United States' position on the importance of patent rights.⁴¹

C. Past Supreme Court Interpretations of the "Safe Harbor" Provision

The difficulty of interpreting the scope of 35 U.S.C. § 271(e)(1) is apparent through both the Supreme Court's and Federal Circuit's varying decisions. There have been several recent Supreme Court cases that have addressed the interpretation of the scope of 35 U.S.C. § 271(e)(1)'s safe harbor provision, including *Eli Lilly & Co. v. Medtronic, Inc.* and *Merck KGaA v. Integra Lifesciences I, Ltd.* Both of these cases addressed pre-marketing approval mechanisms.⁴² In *Eli Lilly*, the Court interpreted 35 U.S.C. § 271(e)(1) to extend to medical devices as well as drugs, based on the plain language of the statute.⁴³ Prior to making its way to the Supreme Court, the Federal Circuit decided the case by using the legislative history to interpret the meaning of the statute.⁴⁴ In contrast, the Supreme Court initially looked at the legislative history but ultimately disregarded it, reasoning that if the legislative intent was to single out drugs, "there were available infinitely more clear and simple ways of expressing that intent."⁴⁵ The decision broadened the scope of the safe harbor provision by holding that Section 271(e)(1) exempts from infringement the use of patented inventions reasonably related to the development and submission of information needed to obtain marketing approval of medical devices under the FDCA.⁴⁶

⁴¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

⁴² 496 U.S. 661 (1990).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

In *Merck*, the Supreme Court again broadened the scope of the safe harbor provision. Before reaching the Supreme Court, the Federal Circuit majority (written by Judge Rader) argued that the legislative history and intent of the provision is clear, and interpreted the meaning of the phrase “solely for uses reasonably related...” narrowly by focusing on the word “solely.”⁴⁷ The Supreme Court, instead of focusing its attention on the word “solely,” gave a broad interpretation to “reasonably related.”⁴⁸ This significantly broadened the scope of the safe harbor provision to include pre-clinical experiments used to develop new drugs, not just generics, if they are regularly submitted to the FDA to get approval.⁴⁹ The Court also held that the safe harbor applies even when the experiments are not ultimately submitted to the FDA, as long as they are relevant to the submissions.⁵⁰ This broad interpretation of the safe harbor provision protects “all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”⁵¹ Based on the Supreme Court’s apparent difficulty in interpreting the scope of the safe harbor provision, there is clearly some ambiguity in the language of 35 U.S.C. § 271(e)(1), as well as disparity between the legislative history and the plain language of the statute, which has led to uncertainty as to the true scope of the provision.

D. *Recent Federal Circuit decisions regarding the “safe harbor” application to post-FDA approval activities*

A major uncertainty that has arisen due to the ambiguity of 35 U.S.C. § 271(e)(1) is whether the safe harbor applies to *post*-FDA approval activities. The Supreme Court cases discussed above focus on only pre-approval activities, however, there have been two recent

⁴⁷ 545 U.S. 193 (2005).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 202.

Federal Circuit cases addressing the post-approval issue. Post-approval issues arise when the FDA requires the drug manufacturers to produce information even after the drug has been approved by the FDA. These cases, *Classen Immunotherapies, Inc. v. Biogen IDEC* and *Momenta Pharms, Inc. v. Amphastar Pharms, Inc.*, seem to have contradicting opinions and used different methods of interpretation to reach the decisions.⁵²

In *Classen v. Biogen*, Classen alleged that Biogen and GlaxoSmithKline (collectively “Biogen”) infringed on their patent when those companies participated in studies linking the timing of childhood vaccines to the development of certain diseases, because Classen owned the patent to the methods used by Biogen.⁵³ Classen argued that the 35 U.S.C. § 271(e)(1) safe harbor provision is limited to “activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration.”⁵⁴ Biogen contended that their reporting to the FDA the results from the studies is within the safe harbor provision.⁵⁵ Judge Rader and Judge Newman wrote the majority opinion.⁵⁶ The majority agreed with Classen that the safe harbor provision “does not apply to information that may be routinely reported to the FDA long after marketing approval has been obtained.”⁵⁷ In coming to their conclusion, the majority discussed the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). The court cited from a House Report that the Act “provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would

⁵² 659 F.3d 1057 (Fed. Cir. 2011); 686 F.3d 1348 (Fed. Cir. 2012).

⁵³ 659 F.3d 1057, 1070 (Fed. Cir. 2011).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

occur after expiration of the patent.”⁵⁸ The court argued that the House Report makes it clear that “the legislation concerns premarketing approval of generic drugs,” citing the report’s statement that “the information which can be developed under this provision is the type which is required to obtain approval of the drug.”⁵⁹ “The Report states that ‘the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval.’”⁶⁰

The dissent, written by Judge Moore, disagrees with the majority’s reliance on the legislative history of the Hatch-Waxman Act to interpret the scope of the safe harbor provision. Judge Moore argues that the majority’s interpretation is “contrary to the plain language of the statute and Supreme Court precedent.”⁶¹ He suggests that by looking at the plain language, the statute does not limit the safe harbor to exclusively pre-FDA-approval.⁶² He relies on the Court’s decision in *Merck*, that “there is simply no room in the statute 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 ... Congress exempted from infringement *all* uses of patented compounds ‘reasonably related’ to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs.”⁶³ Moore suggests that the majority relies too heavily on the legislative history. It is undisputed that the safe harbor covers pre-approval activity, but the legislative history does not address whether it covers more than that. “The language Congress chose to enact and that was signed

⁵⁸ 659 F.3d 1057, 1071 citing H.R.Rep. No. 98-857, pt. 1, at 15, 1894 U.S.C.C.A.N. 2647, 2648 (1984).

⁵⁹ *Id.* at 1071.

⁶⁰ *Id.*

⁶¹ *Id.* at 1083.

⁶² *Id.*

⁶³ 659 F.3d, citing *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

into law by the President is plain on its face. There is no ‘pre-approval’ limitation.”⁶⁴ Moore argues that the plain language of the statute is broader than the majority interpreted by basing their interpretation on the legislative history of the Act.⁶⁵ He ultimately goes on to conclude that Biogen was not required by the FDA to perform the specific infringing studies, and “the general administration of drugs or vaccines is not reasonably related to post-approval reporting activities,” so the activities in question were not “reasonably related” to the submission of data to the FDA, so they are not protected under the safe harbor provision.⁶⁶ Following this decision by the Federal Circuit, GlaxoSmithKline filed a petition for certiorari to have this decision reviewed by the Supreme Court of the United States.⁶⁷

The issue in *Momenta Pharms, Inc. v. Amphastar Pharms, Inc.* is whether patented techniques used to test the bioequivalence of generic drugs to generate data required by the FDA after the drug has been approved is protected under the safe harbor provision of 35 U.S.C. § 271(e)(1).⁶⁸ The drug in question is a generic version of Lovenox (enoxaparin), which prevents blood clots. This drug is made up of a unique set of molecules, creating complications when submitting an ANDA, given the difficulty establishing that the generic has the same active ingredients as the existing drug.⁶⁹ The FDA provided criteria (or “standards for identity”) for generic manufacturers to show that generic enoxaparin has the same active ingredients as Lovenox, and it suggested multiple techniques for this testing.⁷⁰ Amphastar filed an ANDA for generic enoxaparin in March 2003 and obtained FDA approval to market the drug in September

⁶⁴ Id. at 1083.

⁶⁵ Id.

⁶⁶ Id. at 1084.

⁶⁷ *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078 (Feb. 28, 2012).

⁶⁸ 686 F.3d 1348 (Fed. Cir. 2012).

⁶⁹ Id. at 1350.

⁷⁰ Id. at 1350-51.

2011.⁷¹ Amphastar was the first company to file an ANDA for generic enoxaparin.⁷² Subsequently, Momenta Pharmaceuticals, Inc. and Sandoz, Inc. (collectively “Momenta”) obtained FDA approval in July 2010 and were the first to actually bring the drug to the market.⁷³ Momenta patented the “methods for analyzing heterogeneous populations of polysaccharides ... for the presence or amount of a non-naturally occurring sugar ... that results from a method of making enoxaparin...”⁷⁴ As the only generic on the market, Momenta’s sale of enoxaparin generated over a billion dollars per year, largely because of the lack of competition.⁷⁵ Momenta alleged patent infringement because Amphastar used Momenta’s patented methods to analyze enoxaparin samples for manufacturing it for commercial sale.⁷⁶ Amphastar argued that the alleged infringing testing is protected by the Hatch-Waxman safe harbor provision, or 35 U.S.C. § 271(e)(1).⁷⁷

The district court held that “the alleged infringing activity involves the use of plaintiffs’ patented quality control testing methods on each commercial batch of enoxaparin that will be sold after FDA approval” and concluded that the safe harbor does not apply.⁷⁸ The court focused on the legislative history of the safe harbor provision and referenced the *Classen* decision (“although the safe harbor provision permits otherwise infringing activity that is conducted to obtain regulatory approval of a product, it does not permit a generic manufacturer to continue in that otherwise infringing activity after obtaining such approval.”)⁷⁹ Amphastar appealed, arguing that the ruling construed the safe harbor provision too narrowly and suggested that the

⁷¹ Id. at 1351.

⁷² Id.

⁷³ Id.

⁷⁴ 686 F.3d 1348 citing United States Patent No. 7,575,886 col.4 II.53-55.

⁷⁵ Id. at 1351.

⁷⁶ Id. at 1352.

⁷⁷ Id.

⁷⁸ Id. at 1353 citing J.A. 31.

⁷⁹ Id. at 1353.

plain language of the statute does not preclude post-FDA-approval activities.⁸⁰ On appeal, Momenta used *Classen* to argue that the district court was correct. “In *Classen*, this court squarely held that ‘[t]he [safe harbor] does not apply to information that may be routinely reported to the FDA long after marketing approval has been obtained.’”⁸¹ Momenta additionally argued that the FDA does not require the particular patented procedure, so the safe harbor should not apply because there are other acceptable testing methods available.⁸²

Judge Moore and Judge Dyk comprised the majority in the *Momenta* decision, while Judge Rader wrote a lengthy dissent. Notably, Judge Moore wrote the dissent in *Classen* and Judge Rader wrote the majority opinion. Here, the majority looked at the language of the statute to determine the scope of the Hatch-Waxman safe harbor provision.⁸³ The majority looked at the text of the safe harbor provision and did not find any ambiguity in that language after undertaking a plain language interpretation, stating that “Congress could not have been clearer in its choice of words: as long as the use of the patented invention is solely for uses ‘reasonably related’ to developing and submitting information pursuant to ‘a Federal law’ regulating the manufacture, use, or sale of drugs, it is not ‘an act of infringement.’”⁸⁴

The majority posits that although the provision was enacted in the context of the ANDA approval process, Congress used “flexible and expansive” language rather than specifically referencing the ANDA portion of the Food, Drug, and Cosmetic Act.⁸⁵ The majority asserts that if Congress had intended to provision to be limited to exclusively information submitted

⁸⁰ 686 F.3d 1348, 1353.

⁸¹ Appellee’s Br. At 43 (quoting *Classen*, 659 F.3d at 1070, alterations made by Momenta).

⁸² 686 F.3d 1348, 1353 (Fed. Cir. 2012).

⁸³ Id. at 1353-4.

⁸⁴ 686 F.3d 1348, 1354 (Fed. Cir. 2012).

⁸⁵ Id.

pursuant to the FDCA, it would have used more specific language to indicate that intention.⁸⁶ In other places in the statute, there are limitations based on the FDCA that are expressly referenced, such as 35 U.S.C. § 271(e)(2), whereas there are no express references to the FDCA in the safe harbor provision.⁸⁷ The majority stated that it “will not import the limitation of § 271(e)(2) into § 271(e)(1)... The statute here applies to *any* use of a patented invention as long as the use is ‘reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs...’”⁸⁸ Comparing the inclusion of limitations in 35 U.S.C. § 271(e)(2) to the lack of language indicating a limitation in 35 U.S.C. § 271(e)(1), the majority interpreted Congress’ lack of a limitation in 35 U.S.C. § 271(e)(1) to be intentional.⁸⁹ “When the intent of Congress is expressed so clearly and consistently throughout the statute, there is neither need nor the occasion to refer to the legislative history.”⁹⁰ The majority insisted that the legislative history is irrelevant in determining the scope of the safe harbor provision, because Congress would have included language to limit the provision to pre-approval activities if it intended that the provision be so limited.⁹¹

The scope of the Hatch-Waxman safe harbor does not stop at activities reasonably relate to development of information submitted in an ANDA... [a]s long as the allegedly infringing use is ‘for uses reasonably related’ to the development and submission of that information it is not an act of infringement, regardless of where that requirement resides in the law.⁹²

The majority compares this interpretation to the Supreme Court cases addressed above, *Eli Lilly v. Medtronic* and *Merck v. Integra*, in which the Court relied on the statutory language rather than the legislative history to interpret 35 U.S.C. § 271(e)(1). It specifically suggests that the

⁸⁶ Id.

⁸⁷ Id. at 1355.

⁸⁸ Id.

⁸⁹ 686 F.3d 1348, 1355 (Fed. Cir. 2012).

⁹⁰ Id.

⁹¹ Id.

⁹² Id.

Court in *Merck* explicitly rejected the notion that the safe harbor was limited to “the activities necessary to seek approval of a generic drug.”⁹³

The majority ultimately determined that the information obtained by Amphastar using the patented technique is information “submitted” for purposes of the statute.⁹⁴ In response to Momenta’s contention that the information obtained using the patented technique was not “submitted” to the FDA, “but rather was retained by the ANDA holder,” the majority concluded that the FDA requires that this type of information be retained by the manufacturer for each batch of the generic drug produced for one year, and the FDA has the authority to inspect those records at any time for continued approval.⁹⁵ “We think that the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA... the fact that the FDA does not in most cases actually inspect the records does not change the fact that they are for the ‘development and submission of information under a federal law.’”⁹⁶ The court cites *Merck* to support its conclusion that there is no infringement when “there [was] a reasonable basis for believing that the experiments [would] produce the types of information that are relevant to an IND or NDA” regardless of whether that information was actually submitted to the FDA.⁹⁷

The majority found it necessary to distinguish this case from the decision in *Classen*. The majority posits that the specific studies at issue in *Classen* were not mandated by the FDA, instead, only the information about adverse side effects acquired as a result of the studies (which

⁹³ Id.

⁹⁴ 686 F.3d 1348, 1355 (Fed. Cir. 2012).

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Id. citing *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

used the patented method) was required by the FDA.⁹⁸ “This case, however, fits well within *Classen* because the information submitted is necessary both to the continued approval of the ANDA and to the ability to market the generic drug. Here, the submissions are not ‘routine submissions’ to the FDA, but instead are submissions that are required to maintain FDA approval.”⁹⁹ The majority asserts that:

unlike *Classen* where the patented studies performed were not mandated by the FDA, the information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow... Under a proper construction of 35 U.S.C. § 271(e)(1), the fact that Amphastar’s testing is carried out to ‘satisfy the FDA’s requirements means it falls within the scope of the safe harbor, even though the activity is carried out after approval... Unlike *Classen*, where the allegedly infringing activity ‘may’ have eventually led to an FDA submission, there is no dispute in this case that Amphastar’s allegedly infringing activities are carried out to ‘satisfy the FDA’s requirements.’¹⁰⁰

The majority suggests that the court should not adopt the district court’s pre/post-approval distinction, and that “*Classen* did not turn on this artificial distinction” either.¹⁰¹ Additionally, the majority concludes that the safe harbor provision is not limited to situations where the patented invention is the only way to submit the information required by the FDA. The safe harbor still applies even when there are non-infringing alternatives available to the generic manufacturer.¹⁰²

Judge Rader, in his lengthy dissent, disagrees with the majority’s expansive interpretation of the safe harbor provision, arguing that “this expansion of the law circumvents the purpose of the law and ignores the binding precedent of *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed.Cir.2011). Sadly this result will render worthless manufacturing test method

⁹⁸ 686 F.3d 1348, 1358 (Fed. Cir. 2012).

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 1358-9.

¹⁰¹ *Id.*

¹⁰² *Id.* at 1359.

patents.”¹⁰³ He asserts that the interpretation of 35 U.S.C. § 271(e)(1) should rely on the legislative history of the Act, not the plain language of the statute.¹⁰⁴ In his argument, he references *Eli Lilly*, where the Court noted that “[t]he Supreme Court has observed that the text alone of 35 U.S.C. § 271(e)(1) can be ‘not plainly comprehensible.’”¹⁰⁵ In support of his argument for using the legislative history to interpret the provision, Judge Rader refers to multiple legislative history materials, such as House Reports, statements and letters, and Congressional testimony, to show that the intended scope of the Act was limited to only pre-approval testing necessary for FDA approval.¹⁰⁶ “Nowhere in the legislative history can this court find any mention of the post-approval, continuous, commercial sales allowed by this decision.”¹⁰⁷ He suggests that “[s]pecifically, § 271(e)(1) won approval because it was limited in time, quantity, and type,” and that “time” applies to exclusively pre-marketing approval.¹⁰⁸ He emphasizes that the authors of the Hatch-Waxman Act undoubtedly intended for the provision to be limited in these ways. “In particular, the authors made clear that section 271(e)(1) would not apply to commercial sales, i.e., the ‘infringing’ product would not enter the market until *after* the patent’s life.”¹⁰⁹ Judge Rader himself was present during the drafting of this Act. He insists that “[t]he authors of this section (and I hesitate to add that I was present through this legislative process) did not imagine that § 271(e)(1) would allow *continuous, commercial* infringing sales during any portion of the life of the patent.”¹¹⁰ Judge Rader suggests that the majority’s opinion is completely contrary to the Congress’ intent during the legislative process, and the way the majority “rewrites” the law will allow Amphastar to infringe

¹⁰³ Id. at 1362.

¹⁰⁴ Id.

¹⁰⁵ Id. citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

¹⁰⁶ 686 F.3d 1348, 1366 (Fed. Cir. 2012).

¹⁰⁷ Id.

¹⁰⁸ Id. at 1365.

¹⁰⁹ Id.

¹¹⁰ Id. at 1366

throughout the entire life of Momenta’s patent for commercial purposes, competing with Momenta.¹¹¹ Judge Rader goes on to argue that the majority did not consider the word “solely” in its interpretation of the statute.¹¹² He suggests that Amphastar uses the patented method for commercial purposes, not “solely” for developing and submitting information to the FDA.¹¹³

Judge Rader also disagrees with the majority’s interpretation of “submission.”¹¹⁴ He argues that “[m]aintaining or keeping a document has the exact opposite meaning of submitting a document. In other words, ‘submission’ means not really submitting anything – a strange construction of an ‘unambiguous’ term.”¹¹⁵ Rader contends that the statutory language, as well as the legislative history of the statute make it clear that its intended scope is for pre-FDA-approval activity only. “Therefore, a reading of *all* the words in the statute and a reading of those words in light of their legislative history shows that § 271(e)(1) only permits a limited amount of pre-approval experiments to obtain FDA approval.”¹¹⁶ In his analysis, Judge Rader relies on the *Classen* decision and their use of the legislative history, as well as Supreme Court precedent.¹¹⁷ He fully rejects the majority’s effort to distinguish *Classen*, highlighting that Judge Moore’s dissent in *Classen* references the distinction between pre- and post-approval activities, although in her majority here, she insists that *Classen* does not distinguish in this way.¹¹⁸ Additionally, the parties and amici interpreted *Classen* to distinguish pre- and post-approval activities.¹¹⁹ He also expresses his disapproval of the majority’s characterization of

¹¹¹ 686 F.3d 1348, 1366 (Fed. Cir. 2012)

¹¹² Id. at 1367

¹¹³ Id.

¹¹⁴ Id.

¹¹⁵ Id.

¹¹⁶ 686 F.3d 1348, 1367 (Fed. Cir. 2012)

¹¹⁷ Id. at 1367-8

¹¹⁸ Id.

¹¹⁹ Id. at 1368 citing *Classen’s* Opposition to Petition for Rehearing En Banc, at 1.

activities mandated or not mandated by the FDA.¹²⁰ Lastly, Judge Rader asserts that the Supreme Court’s *Eli Lilly* and *Merck* decisions support the *Classen* decision, not the majority’s opinion in this case.¹²¹ Those cases dealt only with pre-approval activity and submissions, and the majority “takes phrases from those opinions out of context to allege that its new interpretation of 35 U.S.C. § 271(e)(1) is consistent with those cases.”¹²²

After the Federal Circuit decided *Momenta* in August, Momenta filed a Petition for Rehearing En Banc. Momenta argued that the panel decision in *Momenta* is contrary to the *Classen* decision.¹²³ Momenta suggested that “[t]he panel’s interpretation expands Section 271(e)(1)’s safe harbor into a safe ocean,” and “nothing in the text or purpose of Section 271(e)(1) warrants the panel’s expansive reading.”¹²⁴ The petition highlighted the inconsistencies between the *Classen* and *Momenta* decisions and relied on Judge Rader’s arguments in *Momenta*’s dissent.¹²⁵ In addition, Momenta’s petition detailed the implications of having uncertainty as to the scope of the safe harbor provision, making it necessary for the court to resolve the inconsistency.¹²⁶ In September, shortly after Momenta filed this petition, Classen Immunotherapies submitted a brief of amicus curiae in support of Momenta’s petition for rehearing en banc.¹²⁷ In its brief, Classen urged the Federal Circuit to reevaluate the outcome in *Momenta* by suggesting that the outcome was in “direct and irreconcilable conflict with the decision” in *Classen* and by discussing the impact it will have on whether the Supreme Court

¹²⁰ Id. at 1369.

¹²¹ Id.

¹²² 686 F.3d 1348, 1370 (Fed. Cir. 2012).

¹²³ *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, Petition for Rehearing En Banc, Nos. 2012-1262, -1103, -1104 at 1.

¹²⁴ Id. at 3.

¹²⁵ Id.

¹²⁶ Id. at 9-10.

¹²⁷ *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, Brief of Amicus Curiae Classen Immunotherapies, Inc. In Support of the Petition for Rehearing En Banc, Nos. 2012-1062, -1103, -1104.

grants certiorari in the *Classen* case.¹²⁸ Classen insisted “the two decisions cannot logically coexist, because Section 271(e)(1) cannot simultaneously be restricted to protecting only pre-marketing uses of patented invention as it was written, and also be expanded to protect some post-marketing activities.”¹²⁹ Classen argued that the effect of the *Momenta* decision is contrary to the purpose of patent laws.¹³⁰ Despite *Momenta*’s petition and Classen’s amicus brief urging the Federal Circuit to reevaluate the panel’s decision in *Momenta*, the Court of Appeals for the Federal Circuit denied the petition for rehearing en banc on November 20, 2012.¹³¹

As mentioned above, GlaxoSmithKline filed a petition for certiorari to the Supreme Court following the Federal Circuit’s decision in *Classen*.¹³² In December, the United States submitted an amicus brief discouraging the Supreme Court from granting the petition for certiorari.¹³³ Although the United States expressed its view that the Federal Circuit erred in the *Classen* decision, the United States concludes that “there is no longer any practical need for this Court’s intervention in light of the Federal Circuit’s subsequent decision in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*”¹³⁴ The brief details the reasons the Federal Circuit’s *Momenta* decision came out correctly. The United States suggests that

Congress not only contemplated that drug manufacturers would conduct post-approval scientific studies and clinical trials, but specifically authorized the FDA to require such studies in a variety of circumstances. If such post-approval studies involve the use of patented inventions solely for uses reasonably related to the development and submission

¹²⁸ Id. at iv.

¹²⁹ Id. at 1-2.

¹³⁰ Id. at 3.

¹³¹ 2012-1062 Docket entry No. 86 (Fed. Cir. Nov. 20, 2012).

¹³² *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, Petition for a Writ of Certiorari (February 28, 2012).

¹³³ Brief for the United States as Amicus Curiae, No. 11-1078 (Dec. 2012).

¹³⁴ Id. at 10.

of information to the FDA, the plain language of Section 271(e)(1) precludes any claim for patent infringement.¹³⁵

The United States’ reasoning primarily relies on the plain language interpretation of the safe harbor provision, noting that “nothing in the language of the statute links the availability of Section 271(e)(1)’s safe harbor to the timing of FDA marketing approval.”¹³⁶ The brief addressed the Supreme Court’s decisions in *Merck* and *Eli Lilly* and determined that those decisions do not allow the court of appeals to conclude that the safe harbor only protects pre-approval activity.¹³⁷ Despite the United States’ in-depth reasoning about why the Federal Circuit came to the wrong conclusion in *Classen*, the United States ultimately determined that there is no need for the Supreme Court to grant certiorari given the Federal Circuit’s decision in *Momenta*, and accepted *Momenta*’s narrow interpretation of *Classen*. On January 14, 2013 the Supreme Court of the United States denied the petition for certiorari.¹³⁸

III. ANALYSIS

The inconsistent decisions in *Classen* and *Momenta* have created an intra-circuit split within the Federal Circuit. The two cases are far too similar for the different outcomes they generated. Although the majority in *Momenta* briefly attempts to distinguish it from the *Classen* decision, this was a weak attempt and is addressed in only a few sentences. The majority suggests that its decision in *Momenta* fits within a narrowly construed *Classen* opinion. The majority argues that “the submissions are not “routine submissions” to the FDA, but instead are

¹³⁵ Id. at 10.

¹³⁶ Id. at 11.

¹³⁷ Id. at 12.

¹³⁸ Order List: 568 U.S. (Jan. 14, 2013).

submissions that are required to maintain FDA approval.”¹³⁹ It also highlights that “unlike *Classen* where the patented studies performed were not mandated by the FDA, the information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow. Under such circumstances, the information can be said to have been gathered solely for submission to the FDA and not, as in *Classen*, primarily for non-FDA purposes...”¹⁴⁰

Judge Rader disagrees with this reasoning in his dissent, stating that this decision “ignores the binding precedent of *Classen*.”¹⁴¹ Judge Rader, who wrote the majority opinion in *Classen*, makes it incredibly clear in his dissent that he does not think the *Momenta* decision can be reconciled with the outcome in *Classen*.¹⁴² There is clearly some inconsistency with the court’s decisions. In addition, Judge Rader himself was involved in the drafting of the Hatch-Waxman Act. He witnessed firsthand the discussions addressing the purposes of the Act and was aware of Congress’ intentions regarding it. Judge Rader argues that the court should primarily use the legislative history to interpret the scope of the safe harbor provision, which he did in *Classen*, and that the majority in *Momenta* was wrong for not considering it in their interpretation.¹⁴³ The legislative history clearly suggests that the scope of the safe harbor provision was intended to be very limited in time and scope. The purpose of the provision is to facilitate the lengthy FDA approval process for generic manufacturers. The safe harbor provision is included in the statute so that generic drugs can obtain FDA approval faster and more easily, which suggests that the scope should be limited to activities before the drug obtains approval from the FDA.

¹³⁹ 686 F.3d 1348 (Fed. Cir. 2012)

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 1362

¹⁴² 686 F.3d 1348, (Fed. Cir. 2012)

¹⁴³ *Id.* at 1362

The core of the issue lies in how the court should go about interpreting the statute. Courts generally look first at the plain language of the statute to interpret its meaning.¹⁴⁴ If there are no ambiguities in the wording of the text, the courts construe the meaning of the statute simply by looking at the language used.¹⁴⁵ However, if the court finds that there are ambiguities in the plain language of the statute, the court will usually look to sources outside the text of the statute itself, such as the legislative history, to determine what Congress intended the statute to mean.¹⁴⁶ Here, the *Classen* majority found that there was ambiguity in the text of Section 271(e)(1).¹⁴⁷ The words “solely,” “reasonably related,” “development and submission” and “federal law which regulates... drugs” are terms that the *Classen* court argued were ambiguous and could not be interpreted simply by looking exclusively at the words of the statute.¹⁴⁸ For this reason, the court found it necessary to look into the legislative history of the Hatch-Waxman Act in order to better determine what Congress intended those words to mean in the context of the statute.¹⁴⁹ As discussed above, when the legislative history is taken into consideration, it seems clear that Congress intended Section 271(e)(1) to be limited to information submitted to the FDA in order to obtain FDA approval, and was not intended to cover infringing activities after the drug gained approval. In this respect, *Classen* interpreted the statute correctly.

In contrast, the *Momenta* majority bases their decision on the opinion that the plain language of Section 271(e)(1) is clear and unambiguous, and therefore the legislative history

¹⁴⁴ Easterbrook, Frank H., TEXT, HISTORY, AND STRUCTURE IN STATUTORY INTERPRETATION, 17 Harv. J.L. & Pub. Pol’y 61 (1994)

¹⁴⁵ Id. at 62

¹⁴⁶ Id.

¹⁴⁷ 659 F.3d 1057, 1070 (Fed. Cir. 2011).

¹⁴⁸ Id.

¹⁴⁹ Id.

should not be taken into account.¹⁵⁰ This majority argued that the legislature carefully picked the words used in the statute and intentionally left out a pre- and post-approval distinction. If the majority is correct that the statutory text is unambiguous, their method of interpretation is also correct. Looking solely at the plain language of the statute, in conjunction with later provisions in the Act, it is reasonable that the statute can be interpreted as including any information kept by the drug manufacturer for submission to the FDA, even if that submission would occur after the drug was approved, and even if the FDA does not actually mandate that the information be submitted. The words in the statute say nothing about the time frame of the submissions and do not limit the scope of the submissions to be requirements under the FDCA. Therefore, without looking into the Congressional intent of the Hatch-Waxman Act, the safe harbor does not appear to be limited to pre-FDA-approval activities.

It then becomes an issue of which Federal Circuit panel used the correct statutory interpretation method in this circumstance. This depends on whether the language in the statute is ambiguous. Two panels of the Federal Circuit came to two almost completely different conclusions as to whether the safe harbor provision applies to post-approval activities. The panels looked at the exact same language in Section 271(e)(1), yet one determined that it does not include post-approval activities, while the other argues that it clearly does. Additionally, the Supreme Court has had to interpret language in Section 271(e)(1) multiple times. A statute that has created so many differences in interpretation, regardless of the methods courts have used to interpret it, would seem to be somewhat ambiguous. The legislative history should be an important tool to interpret what Congress intended the statute to mean.

¹⁵⁰ 686 F.3d 1348 (Fed. Cir. 2012)

Without considering the legislative history of the Hatch-Waxman Act, *Momenta* interprets the scope of the safe harbor provision too broadly. The majority used only the plain text of the provision to analyze its meaning, without taking any of the legislative intent or history into account.¹⁵¹ *Momenta's* approach to interpreting the scope of the safe harbor so broadly creates major implications for the pharmaceutical industry. Allowing the safe harbor to extend to infringing activities after the drug has been approved by the FDA may even extend farther than simply post-approval analytic testing to commercial uses. It would decrease the incentive for brand-name pharmaceuticals to invest time and money into research and development of new drugs. The purpose of the Hatch-Waxman Act was to strike a balance by increasing the market for generics at cheaper prices while still leaving brand-name pharmaceutical companies with incentives to invest in research and development of new drugs. There is a fine line to maintaining this balance, and a broad interpretation of the scope of the safe harbor would skew in favor of generic manufacturers. This would disrupt the balance, especially if generic companies could infringe on patents for producing their drug for commercial purposes. Although a broad interpretation of the scope of the safe harbor provision would disrupt the balance sought by the creators of the Hatch-Waxman Act, an extremely narrow scope would also disrupt that balance and would make it a difficult and slow process to get generics on the market, which would likely increase their costs. When interpreting the scope of the safe harbor provision, the courts need to be mindful of the underlying purposes of the Act.

The conflicting outcomes in *Classen* and *Momenta* create uncertainty within the pharmaceutical industry, and makes the need for a more bright line interpretation of the scope of the safe harbor provision more apparent. This uncertainty as to what activities covered under the

¹⁵¹ 686 F.3d 1348, (Fed. Cir. 2012)

safe harbor is difficult for both the pioneer and generic manufacturers. Generic manufacturers will not know if they are able to use patented techniques to submit information to the FDA after their ANDA has been approved. Pioneer drug manufacturers will be hesitant to invest in developing techniques that may be used freely by generic manufacturers for commercial use, which will compete with their own drugs throughout the life of the patent. When the statute is interpreted in light of the legislative history, it seems apparent that the safe harbor provision does not extend to post-FDA approval activities, however the plain language of the statute, taken without consideration of the legislature's intent, allows for a reasonably broader interpretation of the safe harbor provision because nothing in the statute explicitly prohibits its application to post-FDA-approval activities. As is apparent from the *Merck* and *Eli Lilly* cases, even the Supreme Court has struggled with how far the safe harbor extends.¹⁵² If the plain language of the provision were completely unambiguous, the courts would not be struggling as they to interpret the scope. As mentioned above, this uncertainty will cause brand-name pharmaceutical manufacturers to be wary of investing large amounts of time and money on developing techniques that will be used by generic manufacturers for commercial purposes after the drug is approved by the FDA.

A resolution to this uncertainty is essential for the balance between patent protection and ability for generics to enter the market. This issue can be resolved by a Supreme Court decision that explicitly draws a distinction between pre- and post-FDA-approval activities and makes it clear whether or not they are covered under the safe harbor provision. Alternatively (or additionally), the legislature can address the ambiguity in the wording of the statute. A third option is action by the FDA itself. The FDA could create guidelines allowing or disallowing the

¹⁵² *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

safe harbor to apply to post-approval activities. There are multiple routes available to resolve the ambiguous scope of the safe harbor.

A Supreme Court decision addressing the scope of the safe harbor provision would provide precedent for courts to follow in future infringement cases and would create uniformity in those decisions. Although the Supreme Court denied certiorari in *Classen*, it has another chance to resolve the issue by accepting Momenta's recent petition for certiorari. In its petition, Momenta stresses how important it is that the Supreme Court clarify the scope of the safe harbor provision. It is possible that the Supreme Court denied certiorari for *Classen* because it anticipated a petition after the *Momenta* decision and decided this would be a better opportunity to address the issue. If the Court accepts the petition for certiorari, this would be the most immediate solution to the intra-circuit split. Once the Supreme Court addresses the scope of the safe harbor provision and settles on whether it applies to post-FDA-approval activities, the uncertainty created by the intra-circuit split will be eliminated. The courts below, including the split Federal Circuit, will have guidance in deciding future post-approval infringement cases. This will postpone or eliminate the need for the legislature to amend the wording of the statute or for the FDA to create guidelines. A Supreme Court decision clarifying the scope of the safe harbor provision will be the fastest and most efficient way to provide more certainty for the pharmaceutical industry by allowing manufacturers to predict the outcome of future infringement cases.

If the Supreme Court denies Momenta's petition for certiorari, the legislature might need to address the issue by altering the text of the safe harbor provision. Clearly there have been issues interpreting the meaning of certain terms and phrases in 35 U.S.C. § 271(e)(1) regarding both pre- and post-approval activities. The courts have not always taken the legislative history

and intent into account in their decisions, so the legislature may need to decide what the scope of the provision should be and alter the language to make their intent more clear. Specifically, the legislature might choose re-write the statute to explicitly state whether or not it applies to post-FDA-approval activities. The uncertainty seems to lie in the wording “solely for uses reasonably related to the development and submission of information,”¹⁵³ so that is what Congress should focus on clarifying. Congress could clarify by adding text explicitly saying that this applies only to pre-approval activities or that it applies to *any* activities used to submit information to the FDA. Alternatively, Congress could add an extra sentence following the provision to make it apparent whether or not the safe harbor applies to post-approval activities in addition to pre-approval activities. This solution would provide clarity for the pharmaceutical industry, however it would be a lengthy process and would not provide an immediate solution to the problem.

Lastly, the FDA could write guidelines to clarify whether the scope of the safe harbor encompasses post-FDA-approval activities. The FDA creates guidance documents for different areas of the food and drug laws that the FDA regulates. These guidelines do not have a binding effect, however reviewing courts will give them deference because it is such a technical area. The FDA already has a category of guidance documents for generics, so it could easily assess whether the pharmaceutical industry should be guided in a particular direction regarding the scope of the safe harbor provision and add a guidance document discussing the suggested interpretation. Although these guidelines would not be binding on the pharmaceutical industry, it would provide helpful guidance for pharmaceutical companies uncertain of whether the safe harbor applies to post-FDA-approval activities. Pharmaceutical manufacturers will most likely

¹⁵³ 35 U.S.C. § 271(e)(1)

follow these guidelines, knowing that courts will give deference to them. This would be a short-term solution if the courts are unable to resolve the problem in the near future.

IV. CONCLUSION

The conflicting *Classen* and *Momenta* decisions have emphasized the struggle the courts are facing interpreting the scope of the safe harbor provision. These two cases have made it clear that scope of the safe harbor depends largely on whether the court relies on the plain language of the statute (resulting in a broad interpretation) or the legislative history of the Hatch-Waxman Act (leading to a much narrower interpretation). *Classen* and *Momenta* each address whether the safe harbor extends to post-FDA-approval activities, however the Federal Circuit used the legislative history approach in *Classen* but the plain language approach in *Momenta*, leading to essentially opposite outcomes. These two decisions have created uncertainty as to the scope of the safe harbor and whether it applies to post-FDA-approval activities, highlighting the need for a more bright-line interpretation. This is likely to create major problems in the pharmaceutical industry, leading brand-name manufacturers to be wary of spending large sums of money on research and development of new drugs, and generic manufacturers will be unsure of what constitutes infringement. Ideally, the Supreme Court will clarify the scope of the safe harbor provision by accepting *Momenta*'s petition for certiorari. If the Court refuses to address the issue, the legislature will need to alter the wording in the statute to clarify the scope or the FDA can create guidelines. Ultimately, the scope of the safe harbor provision will need to be clarified in order to avoid the negative consequences that this uncertainty will create in the pharmaceutical industry.