

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

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I. INTRODUCTION

Two recent Federal Circuit decisions, *Classen Immunotherapies, Inc. v. Biogen Idec*.<sup>1</sup> and *Momenta Pharmaceuticals, Inc. v. Amphastar*,<sup>2</sup> have created an intra-circuit split regarding the scope of the Hatch-

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

<sup>2</sup> See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

Waxman Act's<sup>3</sup> "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.<sup>4</sup> In the past, the issue with interpreting the scope of the safe harbor provision has been exclusively related to pre-market approval activities. *Classen* and *Momenta* address whether the safe harbor provision extends to activities *after* the generic drug has been approved. The panels deciding the two cases used different reasoning and ultimately came to two different conclusions; the *Classen* panel used the legislative history of the statute to interpret the scope of the safe harbor provision to exclude post-FDA-approval methods, while the *Momenta* panel used 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.

This Comment discusses the negative impact that the uncertainty of the safe harbor's scope will have on the pharmaceutical industry. Part II of this Comment details the background of the Hatch-Waxman safe harbor provision and how it influences the seemingly conflicting outcomes in *Classen* and *Momenta*. Part III then addresses 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 temporary and long-term solutions to this uncertainty. Ultimately, this Comment proposes that the best way to define the scope of the safe harbor provision is to have Congress address the issue through statutory amendment to clarify its limits and specifically state whether it applies to post-approval activities; however, a short-term solution is to have the FDA set forth a guidance for the industry to clarify its opinion on the issue.

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<sup>3</sup> 35 U.S.C. §271(e)(1) (2010). The Drug Price Competition and Patent Term Restoration Act, is informally known as the "Hatch-Waxman Act."

<sup>4</sup> *See id.*

## 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.<sup>5</sup> For a drug to enter the market, the FDCA requires that the FDA approve it by determining that it is safe and effective.<sup>6</sup> For a pharmaceutical manufacturer to obtain this approval, it must submit a New Drug Application (“NDA”) to the FDA.<sup>7</sup> This process requires multiple stages and usually takes many years to complete.<sup>8</sup> During the first stage—the preclinical stage—a pharmaceutical sponsor tests the toxicology of the drug by performing synthesis and purification, as well as some limited testing on animals.<sup>9</sup> This stage usually takes three to four years.<sup>10</sup> After the completion of the drug’s preclinical testing, the manufacturer moves ahead to the clinical stage, which requires an Investigative New Drug Application (“IND”) and three clinical phases.<sup>11</sup> 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.<sup>12</sup> This stage is incredibly lengthy and spans between 6 and 11 years.<sup>13</sup> Once that is completed, the manufacturer submits the NDA.<sup>14</sup> 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.<sup>15</sup> The FDA evaluates the drug safety, effectiveness, and labeling to determine whether it will be approved.<sup>16</sup> Once the drug has obtained approval, it can be marketed with FDA regulated labeling.<sup>17</sup> The entirety

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<sup>5</sup> 21 U.S.C. §§ 331, 355(a) (Lexis 2013).

<sup>6</sup> *Id.*

<sup>7</sup> 21 U.S.C.A. §355 (Lexis 2013).

<sup>8</sup> See Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, J AM BOARD FAM MED (2001), [www.medscape.com/viewarticle/405869](http://www.medscape.com/viewarticle/405869).

<sup>9</sup> Synthesis of the drug is the composition process, or putting together the compounds to make the drug. Purification is the process of removing impurities in the chemical components of the drug. 21 U.S.C.A. §355 (Lexis 2013).

<sup>10</sup> See Lipsky & Sharp, *supra* note 8.

<sup>11</sup> 21 U.S.C.A. §355 (Lexis 2013).

<sup>12</sup> *Id.*

<sup>13</sup> See Lipsky & Sharp, *supra* note 8.

<sup>14</sup> *Id.*

<sup>15</sup> 21 C.F.R. §314 (Lexis 2013).

<sup>16</sup> *Id.*

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

of this FDA approval process can take anywhere from eleven to fourteen years.<sup>18</sup>

The lengthy time period required for FDA approval creates implications for both brand-name pharmaceutical manufacturers and generic manufacturers, which 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 significant disincentive to generic manufacturers.<sup>19</sup> 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 these exclusivity benefits because the process required the manufacturers to conduct lengthy clinical trials and await regulatory review before being able to place the drug on the market.<sup>20</sup> This long process cut significantly into the limited term of the patent and, as a result, 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.”<sup>21</sup> On the other end, there was little incentive for manufacturers to develop generic drugs because they were required to wait until after the patent term for the brand name drug ended to initiate the lengthy FDA approval process.<sup>22</sup> 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.

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.”<sup>23</sup> This is designed to give pharmaceutical companies incentive to invest in researching and developing new products.<sup>24</sup> Section 271(a) of the Hatch-

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<sup>18</sup> U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.org> (last visited May 15, 2014).

<sup>19</sup> Hasneen Karbalai, *The Hatch-Waxman (Im)Balancing Act*, HARVARD LEDA, 28 (2003).

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

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> 35 U.S.C. 154 (Lexis 2013).

<sup>24</sup> Hasneen Karbalai, *The Hatch-Waxman (Im)Balancing Act*, HARVARD LEDA, 28 (2003).

Waxman Act 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.”<sup>25</sup> However, § 271 also creates an exemption to this rule of infringement. The Act was executed to amend the FDCA to address “the need for innovative new pharmaceuticals and the availability of less expensive generic drugs.”<sup>26</sup> 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.<sup>27</sup> Prior to the Hatch-Waxman Act, the generic market was neither prevalent nor profitable.<sup>28</sup> The generic drug company was 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 similar safety and effectiveness studies.<sup>29</sup> The extensive time and costs required for generic drug manufacturers to gain FDA approval made it unlikely that the manufacturer would recover its investment. This was a huge disincentive for pharmaceutical manufacturers to invest in developing generic drugs.<sup>30</sup>

The Hatch-Waxman Act was a response to the Supreme Court’s decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which prohibited competitors from performing tests required for FDA approval using patented methods until those patents expired.<sup>31</sup> This ruling 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.”<sup>32</sup> Congress enacted the Hatch-Waxman to overrule *Roche*.<sup>33</sup> Title I of 35 U.S.C. § 271 sets out the procedure for the Abbreviated New Drug Applications (“ANDAs”). This abbreviated procedure allows a generic manufacturer to take advantage of the brand-name manufacturer’s lengthy clinical research procedures. The approval process is expedited, allowing them to enter the market much faster than if they had to go through the clinical

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<sup>25</sup> 35 U.S.C. 271(a) (Lexis 2013).

<sup>26</sup> SCHACHT, WENDY H. & JOHN R. THOMAS, CONG. RESEARCH SERV., RL31379, THE “HATCH-WAXMAN” ACT: SELECT PATENT-RELATED ISSUES, Summary (2002).

<sup>27</sup> *Id.* at 2.

<sup>28</sup> Kristen E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests of Survival of the Fittest?* 57 FOOD & DRUG L.J. 247, 249 (2002).

<sup>29</sup> *Id.* at 250.

<sup>30</sup> *Id.* at 249.

<sup>31</sup> 733 F. 2d 858, 863 (Fed. Cir. 1984).

<sup>32</sup> Behrendt, *supra* note 26, at 250.

<sup>33</sup> H.R.Rep. No. 98-857, pt. 2, at 27 (1984).

research process that new drugs must complete, because they are now able to enter the market as soon as the patent expires.<sup>34</sup>

Section 505(j) of the FDCA addresses the abbreviated process for FDA approval of generic bioequivalent drugs.<sup>35</sup> This provision allows manufacturers to file an ANDA, which rely on the original manufacturer's safety and efficacy test results.<sup>36</sup> The provisions of the ADNA do not require the generic manufacturer to submit its own safety and effectiveness studies.<sup>37</sup> 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.<sup>38</sup> The ANDA also requires the generic manufacturer to show that the generic drug is bioequivalent to the approved drug.<sup>39</sup> 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.<sup>40</sup> Under the ANDA procedure, a drug is "bioequivalent" if:

- (i) 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 (ii) 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.<sup>41</sup>

The bioequivalency requirement for the ANDA, rather than safety and efficacy tests that the NDA requires, allows the generic to be able to receive FDA approval much faster.<sup>42</sup> 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 allowing generic manufacturers to

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<sup>34</sup> See ALLAN M. FOX & ALAN R. BENNET, *THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984*, iii-iv (1987).

<sup>35</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 505(j) (Lexis 2013).

<sup>36</sup> *Id.*

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

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* A generic drug is bioequivalent if it contains the same active ingredient as the original. 21 U.S.C.A. § 355 (Lexis 2013).

<sup>41</sup> 21 U.S.C.A. § 355(j)(8)(B) (Lexis 2013).

<sup>42</sup> See Karbalai, *supra* note 19.

obtain FDA approval during the patent period (without being subject to infringement) and enter the market as soon as the patent expires.<sup>43</sup>

In addition to its creation of ANDAs, Congress included a Safe Harbor in the Hatch-Waxman Act to further incentivize creation of new drugs as well as increase the public's access to cheaper generic drugs.<sup>44</sup> The safe harbor provides that:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>45</sup>

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.”<sup>46</sup> Specifically, the terms “solely,” “reasonably related,” and “development and submission of information” have required courts to contemplate how the statute should be interpreted.<sup>47</sup>

Hatch-Waxman's legislative history provides helpful 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.”<sup>48</sup> 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 further:

In order to complete this application, the generic manufacturer must conduct certain drug tests. In order to complete this type of

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<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> 35 U.S.C. § 271(e)(1) (2010).

<sup>46</sup> Karbalai, *supra* note 19, at 28.

<sup>47</sup> *Id.*

<sup>48</sup> Chenwei Wang, *In Search of the Boundary of the Safe Harbor*, 19 FED. CIR. B.J. 617 (2010).

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.*<sup>49</sup>

The legislative history also suggests that the safe harbor is intended to allow for activities only in preparation for commercial activity. In a House floor debate, Representative Kastenmeier stated 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.”<sup>50</sup> Congress intended only minimal interference with a patent holder’s rights through application of this provision. As stated in the House Report: “[T]he 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.”<sup>51</sup> Congress had several concerns regarding the safe harbor provision during the enactment process, including “[t]aking property rights away from people and away from companies”<sup>52</sup> 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.”<sup>53</sup> There were also concerns that this leniency on patent infringement would contradict the United States’ position on the importance of patent rights.<sup>54</sup>

#### *B. The Supreme Court’s Variant 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 § 271(e)(1)’s safe harbor provision, including *Eli Lilly & Co. v. Medtronic, Inc.*<sup>55</sup> and *Merck*

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<sup>49</sup> 130 Cong. Rec. at H8708, (Aug. 4, 1984) (statement of Rep. Robert Kastenmeier) (emphasis added).

<sup>50</sup> *Id.* (emphasis added).

<sup>51</sup> H.R. Rep. No. 98-857, pt. 2, at 8 (1984).

<sup>52</sup> 130 Cong. Rec. at H8710 (Aug. 4, 1984) (statement of Rep. Michael DeWine).

<sup>53</sup> 130 Cong. Rec. at H8710 (Aug. 4, 1984) (statement of Rep. William Moorhead).

<sup>54</sup> *See generally* *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

<sup>55</sup> 496 U.S. 661 (1990).



*KGaA v. Integra Lifesciences I, Ltd.*<sup>56</sup> Both of these cases addressed pre-marketing approval mechanisms.<sup>57</sup> In *Eli Lilly*, the Court interpreted § 271(e)(1) to extend to medical devices as well as drugs, based on the plain language of the statute.<sup>58</sup> This was a departure from the decision below, where the Federal Circuit decided the case by using the legislative history to interpret the meaning of the statute.<sup>59</sup> 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.”<sup>60</sup> The decision broadened the scope of the safe harbor provision by holding that § 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.”<sup>61</sup>

In *Merck*, the Supreme Court again broadened the scope of the safe harbor provision. Before reaching the Supreme Court, the Federal Circuit majority opinion 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.”<sup>62</sup> The Supreme Court, rather than focusing its attention on the word “solely,” hung its analysis on a broad interpretation of the term “reasonably related.”<sup>63</sup> 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.<sup>64</sup> 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.<sup>65</sup> 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.”<sup>66</sup> Based on the Supreme Court’s apparent difficulty in interpreting the scope of the safe harbor provision,

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<sup>56</sup> 545 U.S. 193 (2005).

<sup>57</sup> See generally *Merck*, 545 U.S. 193; *Eli Lilly*, 496 U.S. 661.

<sup>58</sup> 496 U.S. at 661.

<sup>59</sup> *Id.* at 668–69.

<sup>60</sup> *Id.* at 667.

<sup>61</sup> *Id.* at 661.

<sup>62</sup> See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205 (2005).

<sup>63</sup> *Id.* at 204–05.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 207–08.

<sup>66</sup> *Id.* at 202 (emphasis in original).

there is clearly some ambiguity in the language of § 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.

*C. The Federal Circuit's Recent Inconsistency Regarding the "Safe Harbor's" Application to Post-FDA Approval Activities*

A major uncertainty that has arisen due to the safe harbor's ambiguity is whether it applies to *post*-FDA approval activities. *Eli Lilly* and *Merck* focused on only pre-approval activities.<sup>67</sup> However, there have been two recent Federal Circuit cases addressing the post-approval issue.<sup>68</sup> These issues arise when the FDA requires the drug manufacturers to produce information even after the drug has been approved. A review of the cases demonstrates that the Federal Circuit has produced contradicting opinions and different methods of interpretation to resolve factually similar disputes.<sup>69</sup>

In *Classen*, Classen alleged that Biogen and GlaxoSmithKline (collectively "Biogen") infringed on its patent by participating in studies linking the timing of childhood vaccines to the development of certain diseases, because Classen owned the patent to Biogen's methods.<sup>70</sup> Classen argued that § 271(e)(1)'s safe harbor provision is limited to "activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration."<sup>71</sup> Biogen contended that its reporting to the FDA the results from the studies fell squarely within the safe harbor provision.<sup>72</sup> Judges Rader and Newman wrote the majority opinion, agreeing 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."<sup>73</sup> In coming to its conclusion, the majority discussed the legislative history of the Hatch-Waxman Act. The court pointed to the House Report, that provided 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

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<sup>67</sup> See *supra* note 54 and accompanying text.

<sup>68</sup> See generally *Momenta Pharms, Inc. v. Amphastar Pharms, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).

<sup>69</sup> See generally *Momenta Pharms, Inc. v. Amphastar Pharms, Inc.*, 686 F.3d 1348 (Fed. Cir. 2012); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).

<sup>70</sup> *Classen*, 659 F.3d at 1070.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

approval if marketing of the drug would occur after expiration of the patent.”<sup>74</sup> The court found that the House Report makes it clear that “the legislation concerns [only] premarketing approval of generic drugs,” specifically citing the Report’s statement that “[t]he information which can be developed under this provision is the type which is required to obtain approval of the drug.”<sup>75</sup> Importantly, “[t]he 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.’”<sup>76</sup>

The dissent, written by Judge Moore, disagreed with the majority’s reliance on the legislative history of the Act to interpret the scope of the safe harbor provision. Judge Moore argued that the majority’s interpretation is “contrary to the plain language of the statute and Supreme Court precedent.”<sup>77</sup> He suggested that by looking at the plain language, the statute does not limit the safe harbor to exclusively pre-FDA-approval.<sup>78</sup> He relied on the Court’s decision in *Merck*, which provided 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.<sup>79</sup>

Moore suggested that the majority relied 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 into law by the President is plain on its face.”<sup>80</sup> Simply put,

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<sup>74</sup> *Id.* at 1071 (citing H.R. REP. No. 98-857, pt. 1, at 15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648).

<sup>75</sup> *Id.* (citing H.R. REP. No. 98-857, pt. 1, at 45 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648).

<sup>76</sup> *Classen*, 659 F.3d at 1071 (citing H.R. REP. No. 98-857, pt. 1, at 30 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648).

<sup>77</sup> *Id.* at 1083 (Moore, J., dissenting).

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 1083 (emphasis in original) (citing *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005)).

<sup>80</sup> *Id.*

“[t]here is no ‘pre-approval’ limitation.”<sup>81</sup> Moore argued that the plain language of the statute is broader than the majority concluded through its reliance on the legislative history.<sup>82</sup> He ultimately concluded 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.”<sup>83</sup> Since the activities in question were not “reasonably related” to the submission of data to the FDA they were not protected under the safe harbor provision.<sup>84</sup> 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, which was denied on January 14, 2013.<sup>85</sup>

The issue in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* was 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 § 271(e)(1).<sup>86</sup> The drug in question is a generic version of Lovenox (enoxaparin), which prevents blood clots.<sup>87</sup> This drug is made 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.<sup>88</sup> 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.<sup>89</sup> Amphastar filed an ANDA for generic enoxaparin in March 2003 and obtained FDA approval to market the drug in September 2011.<sup>90</sup> Amphastar was the first generic manufacturer to file an ANDA for enoxaparin.<sup>91</sup> 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.<sup>92</sup> Momenta patented the “methods for analyzing heterogeneous populations of sulfated

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<sup>81</sup> *Id.*

<sup>82</sup> *Classen*, 659 F.3d at 1083–84.

<sup>83</sup> *Id.* at 1084.

<sup>84</sup> *Id.*

<sup>85</sup> *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 973 (2013) (mem).

<sup>86</sup> *See Momenta Pharms, Inc. v. Amphastar Pharms, Inc.*, 686 F.3d 1348, [1348-51](#) (Fed. Cir. 2012)

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 1349–50.

<sup>89</sup> *Id.* at 1350–51.

<sup>90</sup> *Id.* at 1351.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

polysaccharides . . . ‘for the presence or amount of a non-naturally occurring sugar . . . that results from a method of making enoxaparin.’”<sup>93</sup> 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.<sup>94</sup> Momenta alleged patent infringement because Amphastar used Momenta’s patented methods to analyze enoxaparin samples for manufacturing it for commercial sale.<sup>95</sup> Amphastar argued that the allegedly infringing method of testing is protected § 271(e)(1)’s safe harbor.<sup>96</sup>

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.<sup>97</sup> The court focused on the legislative history of the safe harbor provision and specifically referenced *Classen* to support its decision.<sup>98</sup> Amphastar appealed, arguing that the ruling construed the safe harbor provision too narrowly, and suggested that the plain language of the statute does not preclude post-FDA-approval activities.<sup>99</sup> On appeal, Momenta relied on *Classen* to urge affirmance of the district court’s ruling, arguing that, “[i]n *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.’”<sup>100</sup> 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.<sup>101</sup>

In *Momenta*, Judges Moore and Dyk comprised the majority, while Judge Rader wrote a lengthy dissent. Notably, Judge Moore wrote the dissent in *Classen* and Judge Rader wrote the majority opinion.

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<sup>93</sup> *Momenta*, 686 F.3d at 1351 (citing U.S. Patent No. 7,575,886 col. 4 II. 53-55 (filed 2009-08-18)).

<sup>94</sup> *Id.* at 1351.

<sup>95</sup> *Id.* at 1352.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 1353 (citing J.A. 31).

<sup>98</sup> *Id.* at 1353 (“[A]lthough 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.”).

<sup>99</sup> *Momenta*, 686 F.3d at 1353.

<sup>100</sup> Brief of Plaintiff-Appellees Momenta Pharmaceuticals, Inc. and Sandoz, Inc. at 43, 686 F.3d 1348 (Fed. Cir. 2012) (No. 2012-1062) (quoting *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011)).

<sup>101</sup> *Momenta*, 686 F.3d at 1353.

Here, the majority looked at the language of the statute to determine the scope of Hatch-Waxman's safe harbor provision.<sup>102</sup> The majority looked at the text of the provision and did not find any ambiguity, 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.'"<sup>103</sup>

The majority posited 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 FDCA.<sup>104</sup> The majority asserted that if Congress had intended the provision to be limited exclusively to information submitted pursuant to the FDCA, it would have used more specific language to indicate that intention.<sup>105</sup> In other parts of the statute, there are limitations based on the FDCA that are expressly referenced, such as § 271(e)(2), whereas there are no express references to the FDCA in the safe harbor provision.<sup>106</sup> The majority stated that it "will not import the limitation of § 271(e)(2) into § 271(e)(1)" because the latter "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.'"<sup>107</sup> Comparing the inclusion of limitations in § 271(e)(2) to the lack of language indicating a limitation in § 271(e)(1), the majority interpreted Congress's lack of a limitation in § 271(e)(1) to be intentional.<sup>108</sup> It stated: "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."<sup>109</sup> 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.<sup>110</sup>

The majority found that the scope of the safe harbor extends beyond activities related to information submitted in an ANDA so long

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<sup>102</sup> *Id.* at 1353–54.

<sup>103</sup> *Id.* at 1354.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 1355.

<sup>107</sup> *Momenta*, 686 F.3d at 1355.

<sup>108</sup> *Id.*

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

<sup>110</sup> *Id.*

as the activity is for “uses reasonably related” to the development and submission of information in an ANDA.<sup>111</sup> The majority compared this interpretation to the Supreme Court’s conclusions in *Eli Lilly* and *Merck*, in which the Court relied on the statutory language rather than the legislative history to interpret § 271(e)(1). It specifically suggested that the Court in *Merck* explicitly rejected the notion that the safe harbor was limited to “the activities necessary to seek approval of a generic drug.”<sup>112</sup>

The majority ultimately determined that the information obtained by Amphastar using the patented technique is information “submitted” for purposes of the statute.<sup>113</sup> 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.<sup>114</sup> The majority stated:

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.’<sup>115</sup>

The court cited *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.<sup>116</sup>

Notably, the majority found it necessary to distinguish the case from the decision in *Classen* a year earlier. The majority posited that the FDA did not mandate the specific studies at issue in *Classen*; instead, only the information about adverse side effects acquired as a result of the studies (which used the patented method) was required by the FDA.<sup>117</sup> It

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<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Momenta*, 686 F.3d at 1355.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 1357 (citing *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005)).

<sup>117</sup> *Id.* at 1358.

found that this case “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,” because “the submissions are not ‘routine submissions’ to the FDA, but instead are submissions that are required to maintain FDA approval.”<sup>118</sup> The majority asserted that:

[U]nlike *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.’<sup>119</sup>

The majority rejected the district court’s pre/post-approval distinction because “*Classen* did not turn on this artificial distinction” either.<sup>120</sup> Additionally, the majority concluded 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.<sup>121</sup>

Judge Rader, in his lengthy dissent, disagreed with the majority’s expansive interpretation of the safe harbor provision, arguing that “[t]his expansion of the law circumvents the purpose of the law and ignores the binding precedent of [*Classen*].”<sup>122</sup> Rader lamented that “this result will render worthless manufacturing test method patents.”<sup>123</sup> He asserted that the interpretation of § 271(e)(1) should rely on the legislative history of the Act, not the plain language of the statute.<sup>124</sup> In his argument, he referenced *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

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<sup>118</sup> *Id.*

<sup>119</sup> *Momenta*, 686 F.3d at 1358–59.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at 1359.

<sup>122</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*



comprehensible.”<sup>125</sup> In support of his argument for using the legislative history to interpret the provision, Judge Rader referred 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.<sup>126</sup> “Nowhere in the legislative history,” Judge Rader concludes, “can this court find any mention of the post-approval, continuous, commercial sales allowed by this decision.”<sup>127</sup> He suggested that “[s]pecifically, § 271(e)(1) won approval because it was limited in time, quantity, and type,” and that “time” applies exclusively to pre-marketing approval.<sup>128</sup> He emphasized 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.”<sup>129</sup>

Judge Rader, who was himself present during the drafting of this Act, insisted 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.”<sup>130</sup> His dissent suggested that the majority’s opinion was completely contrary to Congress’s intent during the legislative process, and the way the majority “rewr[ote]” the law will allow Amphastar to infringe throughout the entire life of Momenta’s patent for commercial purposes, competing with Momenta.<sup>131</sup> Judge Rader further argued that the majority did not consider the word “solely” in its interpretation of the statute.<sup>132</sup> He suggested that Amphastar uses the patented method for commercial purposes, not “solely” for developing and submitting information to the FDA.<sup>133</sup>

The dissent also disagreed with the majority’s interpretation of “submission.”<sup>134</sup> Judge Rader argued that “[m]aintaining or keeping a document has the exact opposite meaning of submitting a document. In

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<sup>125</sup> *Momenta*, 686 F.3d at 1362 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990)).

<sup>126</sup> *Id.* at 1366.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* at 1365.

<sup>129</sup> *Id.* at 1366.

<sup>130</sup> *Id.* at 1366 (emphasis in original).

<sup>131</sup> *Momenta*, 686 F.3d at 1366.

<sup>132</sup> *Id.* at 1367.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

other words, ‘submission’ means not really submitting anything – a strange construction of an ‘unambiguous’ term.”<sup>135</sup> He contended that the statutory language and legislative history make it clear that its intended scope is for pre-FDA-approval activity only.<sup>136</sup> “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.”<sup>137</sup> In his analysis, Judge Rader relied on the *Classen* decision’s use of the legislative history, as well as Supreme Court precedent.<sup>138</sup> Rader fully rejected the majority’s effort to distinguish *Classen*, highlighting that Judge Moore’s dissent in *Classen* referenced the distinction between pre- and post-approval activities, while in this opinion he insisted that *Classen* does not distinguish in this way.<sup>139</sup> Additionally, the parties and amici interpreted *Classen* to distinguish pre- and post-approval activities.<sup>140</sup> The dissent also expressed disapproval of the majority’s characterization of activities mandated or not mandated by the FDA.<sup>141</sup> Lastly, Judge Rader asserted that the majority opinion, unlike the decision in *Classen*, went against the Supreme Court’s holdings in *Eli Lilly* and *Merck*.<sup>142</sup> 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.”<sup>143</sup>

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 *Classen*.<sup>144</sup> *Momenta* suggested that “[t]he panel’s interpretation expands Section 271(e)(1)’s safe harbor into a safe ocean,” even though “nothing in the text or purpose of Section 271(e)(1) warrants the panel’s expansive reading.”<sup>145</sup> The petition highlighted the inconsistencies between the *Classen* and *Momenta* decisions and relied on Judge Rader’s arguments in dissent in

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<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Momenta*, 686 F.3d at 1367.

<sup>138</sup> *Id.* at 1367–68.

<sup>139</sup> *Id.* at 1368.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 1369.

<sup>142</sup> *Id.*

<sup>143</sup> *Momenta*, 686 F.3d at 1370.

<sup>144</sup> Petition for Rehearing En Banc, *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F. 3d 1348 (Fed. Cir. 2012) (No. 2012-1262, -1103, -1104).

<sup>145</sup> *Id.* at 3.

*Momenta*.<sup>146</sup> In addition, Momenta's petition detailed the implications of this uncertainty as to the scope of the safe harbor provision, making it necessary for the court to resolve the inconsistency.<sup>147</sup> 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.<sup>148</sup> 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 grants certiorari in the *Classen* case.<sup>149</sup> 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."<sup>150</sup> Classen argued that the effect of the *Momenta* decision is contrary to the purpose of patent laws.<sup>151</sup> Despite Momenta's petition and Classen's amicus brief urging the Federal Circuit to reevaluate the panel's decision in *Momenta*, its petition for rehearing en banc was denied on November 20, 2012.<sup>152</sup>

As noted, GlaxoSmithKline filed a petition for *certiorari* to the Supreme Court following the Federal Circuit's decision in *Classen*.<sup>153</sup> In December of 2012, the United States submitted an amicus brief discouraging the Supreme Court from granting the petition for certiorari.<sup>154</sup> Although the United States expressed its view that the Federal Circuit erred in the *Classen* decision, it concluded 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.*"<sup>155</sup> The brief detailed the reasons the Federal Circuit's *Momenta* decision came out correctly, suggesting that:

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

<sup>147</sup> *Id.* at 9–10.

<sup>148</sup> See generally Brief of Amicus Curiae Classen Immunotherapies, Inc. In Support of the Petition for Rehearing En Banc, 686 F. 3d 1348 (Fed. Cir. 2012) (No. 2012-1062, -1103, -1104).

<sup>149</sup> *Id.* at iv.

<sup>150</sup> *Id.* at 1–2.

<sup>151</sup> *Id.* at 3.

<sup>152</sup> 2012-1062 Docket entry No. 86 (Fed. Cir. Nov. 20, 2012).

<sup>153</sup> See generally Petition for a Writ of Certiorari, *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 659 F.3d 1057 (Fed. Cir. 2012) (No. 11-1078).

<sup>154</sup> Brief for the United States as Amicus Curiae, *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 659 F.3d 1057 (Fed. Cir. 2012) (No. 11-1078).

<sup>155</sup> *Id.* at 10.

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 of information to the FDA, the plain language of Section 271(e)(1) precludes any claim for patent infringement.<sup>156</sup>

The United States' reasoning relied primarily 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."<sup>157</sup> The brief addressed the Supreme Court's decisions in *Merck* and *Eli Lilly* and determined that they do not allow the court of appeals to conclude that the safe harbor only protects pre-approval activity.<sup>158</sup> 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 was 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.<sup>159</sup> The Supreme Court had another opportunity to address the issue when *Momenta* filed a petition for certiorari with the Supreme Court. Despite the need for Supreme Court review, *Momenta*'s petition was denied on June 24, 2013.<sup>160</sup> The Supreme Court did not give a reason for refusing to grant certiorari.<sup>161</sup>

### 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 to produce such disparate outcomes. Although the majority in *Momenta* briefly attempted to distinguish the *Classen* decision, this was a half-hearted attempt detailed in only a few sentences. The majority suggested that its decision in *Momenta* fits within a narrowly construed

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<sup>156</sup> *Id.* at 10.

<sup>157</sup> *Id.* at 11.

<sup>158</sup> *Id.* at 12.

<sup>159</sup> 659 F. 3d 1057 (Fed. Cir. 2011), cert. denied, 133 S. Ct. 973 (2013) (mem).

<sup>160</sup> *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 133 S.Ct. 2854 (2013) (mem).

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

*Classen* opinion, arguing that “the submissions are not ‘routine submissions’ to the FDA, but instead are submissions that are required to maintain FDA approval.”<sup>162</sup> It also highlighted 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.”<sup>163</sup> Here, the information was gathered for the purpose of submitting information to the FDA as opposed to the primarily non-FDA purposes in *Classen*,<sup>164</sup>

In dissent, Judge Rader disagreed with this reasoning, stating that this decision “ignores the binding precedent of *Classen*.”<sup>165</sup> Judge Rader, who wrote the majority opinion in *Classen*, made it clear in his dissent that he does not think the *Momenta* decision can be reconciled with the outcome in *Classen*.<sup>166</sup> There are explicit inconsistencies with the court’s decisions. In addition, Judge Rader himself was present during the drafting of the Hatch-Waxman Act. He witnessed firsthand the discussions addressing the purposes of the Act and was aware of Congress’s intentions regarding it. Judge Rader argued 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.<sup>167</sup> 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.<sup>168</sup> 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.<sup>169</sup>

The core of the issue lies in the proper method of interpreting the statute. Courts generally look first at the plain language of a statute to interpret its meaning.<sup>170</sup> If there are no ambiguities in the wording of the

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<sup>162</sup> *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1358 (Fed. Cir. 2012).

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>166</sup> *Id.* at 1348.

<sup>167</sup> *Id.* at 1362 (Rader, J., dissenting).

<sup>168</sup> *See supra* note 33.

<sup>169</sup> *Id.*

<sup>170</sup> Frank H. Easterbrook, *Text, History, and Structure in Statutory Interpretation*, 17 HARV. J.L. & PUB. POL’Y 61 (1994).

text, the courts construe the meaning of the statute simply by looking at the language used.<sup>171</sup> However, if the court finds that there are ambiguities in the plain language of the statute, it 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.<sup>172</sup> In *Classen*, the majority found that there was ambiguity in the text of § 271(e)(1).<sup>173</sup> 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 properly be interpreted by looking exclusively at the words of the statute.<sup>174</sup> 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 broader context of the statute as a whole.<sup>175</sup> As discussed, when the legislative history is taken into consideration, it seems readily apparent that Congress intended § 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.<sup>176</sup> In this respect, *Classen* interpreted the statute correctly.

In contrast, the *Momenta* majority found that the plain language of § 271(e)(1) is clear and unambiguous and, therefore, that the legislative history should not be taken into account.<sup>177</sup> This majority argued that the legislature carefully picked the words used in the statute and intentionally left out a pre- and post-approval distinction.<sup>178</sup> If the majority is correct that the statutory text is unambiguous, its 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

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<sup>171</sup> *Id.* at 62.

<sup>172</sup> *Id.*

<sup>173</sup> *See Classen Immunotherapies v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011).

<sup>174</sup> *Id.*

<sup>175</sup> *Id.* at 1070–71.

<sup>176</sup> *See generally* H.R. REP. No. 98-857, pt. 1, at 15 (1984), *reprinted in* U.S.C.C.A.N. 2647, 2648.

<sup>177</sup> *See generally* *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348 (Fed. Cir. 2012).

<sup>178</sup> *Id.*

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.<sup>179</sup> 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.

The issue then becomes which Federal Circuit panel properly construed the safe harbor in this circumstance. This depends on whether the language in the statute is ambiguous. Two panels of the Federal Circuit came to two diametrically opposite conclusions as to whether the safe harbor provision applies to post-approval activities.<sup>180</sup> The panels looked at the exact same language in § 271(e)(1), yet one determined that it does not include post-approval activities, while the other argued that it clearly does. Additionally, the Supreme Court has had to interpret the language in § 271(e)(1) multiple times.<sup>181</sup> That a statute can espouse so many variant interpretations, regardless of the methods courts have used, suggests its ambiguous nature. The legislative history is therefore a necessary tool for courts in interpreting what Congress intended the statute to mean.

Without considering the legislative history of the Hatch-Waxman Act, the *Momenta* majority interpreted the scope of the safe harbor provision too broadly.<sup>182</sup> 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.<sup>183</sup> *Momenta's* broad interpretation of the safe harbor's scope has serious implications for the pharmaceutical industry. Allowing the safe harbor to extend to infringing activities after the FDA has approved a drug 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.<sup>184</sup> 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 likely skew in favor

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<sup>179</sup> 35 U.S.C. § 271(e)(1) (2010).

<sup>180</sup> *Compare Momenta*, 686 F.3d at 1355-60, with *Classen*, 659 F.3d at 1070-73.

<sup>181</sup> See generally *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

<sup>182</sup> See *Momenta*, 686 F.3d at 1355-60.

<sup>183</sup> *Id.*

<sup>184</sup> *Momenta*, 686 F.3d at 1362 (Rader, J., dissenting).

of generic manufacturers.<sup>185</sup> This would disrupt the balance, especially if generic companies could infringe on patents for producing their drug for commercial purposes.<sup>186</sup>

However, although a broad interpretation of the scope of the safe harbor would disrupt the balance sought by the creators of the Hatch-Waxman Act, an extremely narrow scope would also disrupt that balance by making it an overly difficult and slow process to get generics on the market, which would likely increase their costs.<sup>187</sup> 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 demonstrate the need for courts to provide a uniform interpretation of the scope of the safe harbor provision. The uncertainty as to which activities are covered under the 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.<sup>188</sup> 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.<sup>189</sup> This uncertainty will cause brand-name pharmaceutical manufacturers to be wary of investing large amounts of time and money on developing techniques that generic manufacturers will use 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. Ultimately, there are multiple routes available to resolve the ambiguous scope of the safe harbor. The ideal solution would have been to have the Supreme Court weigh in and explicitly draw a distinction between pre- and post-FDA-approval activities and make it clear whether or not they are covered under the safe harbor provision. However, the Supreme Court has refused to address the issue by denying both *Classen*'s and *Momenta*'s petitions for certiorari. Without a Supreme Court decision to resolve the issue, Congress may need to address the ambiguity in the wording of the statute. Another option is action by the FDA itself. The

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<sup>185</sup> *Id.*

<sup>186</sup> *Id.* at 1366.

<sup>187</sup> See Karbalai, *supra* note 19.

<sup>188</sup> See *supra* note 69 and accompanying text.

<sup>189</sup> *Id.*



FDA could create guidelines allowing or disallowing the safe harbor to apply to post-approval activities.

A Supreme Court decision clarifying the scope of the safe harbor provision would have been 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. That decision would have provided precedent for courts to follow in future infringement cases and would create uniformity in those decisions. This would have been the most immediate solution to the intra-circuit split and would have postponed or eliminated the need for Congress to amend the wording of the statute or for the FDA to create guidelines. However, the Supreme Court refused to grant *certiorari* for both cases,<sup>190</sup> thereby prolonging the uncertainty and creating the need for an alternate remedy. As the issue stands currently, there is no precedent on which pharmaceutical manufacturers can rely, and the outcomes of future cases will vary.

Since the Supreme Court denied Momenta's petition for certiorari, Congress 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 § 271(e)(1) regarding both pre- and post-approval activities.<sup>191</sup> The courts have not always taken the legislative history and intent into account in their decisions, so Congress may need to provide what the scope of the provision should be and alter the language to make its intent more clear. Specifically, Congress could choose to re-write the statute to explicitly state whether or not it applies to post-FDA-approval activities. Since the uncertainty seems to lie in the wording "solely for uses reasonably related to the development and submission of information,"<sup>192</sup> that is naturally the most sensible starting point for clarification. Congress could clarify by adding text explicitly saying that the safe harbor 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. Either approach would provide clarity for the pharmaceutical industry;

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<sup>190</sup> See *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 973 (2013) (mem.); *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 133 S.Ct. 2854 (2013) (mem).

<sup>191</sup> See *supra* note 68 and accompanying text.

<sup>192</sup> 35 U.S.C. § 271(e)(1) (2010).

however, it would be a lengthy process and would not provide an immediate solution to the problem.<sup>193</sup>

Lastly, the FDA could write guidelines to clarify whether the scope of the safe harbor encompasses post-FDA-approval activities. The FDA routinely creates guidance documents for different areas of the food and drug laws that it is tasked with regulating.<sup>194</sup> While these guidelines do not have a binding effect, reviewing courts will give them deference because it is such a technical area.<sup>195</sup> The FDA already has a category of guidance documents for generics,<sup>196</sup> so it could reasonably 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. This would provide helpful guidance for pharmaceutical companies uncertain of whether the safe harbor applies to post-FDA-approval activities. Pharmaceutical manufacturers will most likely follow these guidelines, knowing that courts will give deference to them.<sup>197</sup> This would be the most probable short-term solution since the Supreme Court is currently unwilling to resolve this issue.

#### IV. CONCLUSION

The conflicting *Classen* and *Momenta* decisions have emphasized the struggle the courts, particularly the Federal Circuit, are facing interpreting the scope of the safe harbor provision. These two cases have made it clear that the 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* and the plain language approach in *Momenta*,

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<sup>193</sup> The FDA is a Federal administrative agency, so it must go through a lengthy process (sometimes called “notice and comment rulemaking”) in order to promulgate new rules as well as amend existing rules. This process requires that the agency notify the public of the proposed regulation, as well as give the public an opportunity to submit comments regarding the proposed regulation before issuing the final regulation or amendment. See 5 U.S.C. § 553 (2006).

<sup>194</sup> See, e.g. U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.org/Drugs/GuidanceandComplianceRegulatoryInformation/Guidances/default.htm> (last visited May 15, 2014).

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> See generally KM Lewis, *Informal guidance and the FDA*, 66(4) FOOD & DRUG L.J. 507 (2011).

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 uniform bright-line interpretation. The persistent lack of clarity 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, while generic manufacturers will be unsure of what constitutes infringement. Since the Court has refused to clarify the scope of the safe harbor provision, either Congress or, at a minimum, the FDA will have to step in and provide meaningful guidance. 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.