SYRACUSE JOURNAL OF SCIENCE & TECHNOLOGY LAW

VOLUME 29 FALL 2013 ARTICLE 6, PAGE 193

Use of Patented Inventions after FDA Approval: How to Define the Hatch-Waxman Safe Harbor in Light of *Momenta* and *Classen*

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Abstract

This paper will discuss the apparent inconsistencies in the recent *Classen v. Biogen* and *Momenta v. Amphastar* decisions by the Court of Appeals for the Federal Circuit regarding the Hatch-Waxman Safe Harbor. Although it is well settled that the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act permits a generic drug company to use the patented invention of another party to develop a generic drug for approval by the United States Food and Drug Administration ("FDA"), the court's recent decisions have raised a question as to whether the safe harbor may protect activity subsequent to FDA approval of the generic drug. Clarification is needed on this issue and should to be provided forthwith by the judiciary. Without judicial guidance, the institutions responsible for the development and financial support of new and generic pharmaceuticals will be plagued by both legal and business uncertainty, which will adversely affect all stakeholders, including patentees, generic drug companies, and consumers.

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Introduction

As is well established, it is an act of infringement to make, use, offer to sell, sell, or import a patented invention without the permission of a patent owner.[1] However, the U.S. Patent Act makes a specific experimental use exception under the Hatch-Waxman Act for uses related to developing generic pharmaceuticals and devices for approval before the United States Food and Drug Administration (FDA).[2] This experimental use exception, known as the Hatch-Waxman safe harbor, allows generic pharmaceutical companies to prepare otherwise infringing material for an Abbreviated New Drug Application ("ANDA") before the FDA. Moreover, it is understood that activity in which the generic company engages to gain approval is not considered infringement.

However, two recent and seemingly contradictory cases before the Court of Appeals for the Federal Circuit ("CAFC") have called into question the extent of this safe harbor: *Classen v. Biogen* (decided August 31, 2011) and *Momenta v. Amphastar* (decided August 3, 2012). In the former, activities conducted after FDA market approval did not receive safe harbor protection.[3] Yet, in the latter, such protection was granted to activities having specific bearing on sales after approval.[4]

This paper will begin with a background of the Hatch-Waxman Act in order to explain the purpose and intent of the law. Recent litigation concerning pertinent cases will then be examined in order to explore how the courts have addressed the Hatch-Waxman safe harbor. The controversy within the CAFC will then be discussed in more detail in order to provide a better understanding of the issue at hand. This paper will then discuss the urgent need for the

[1] 35 U.S.C. § 271(a) (2010).
[2] 35 U.S.C. § 271(e) (2010).
[3] *Classen Immunotherapies v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).
[4] *Momenta Pharm. v. Amphastar Pharm.*, 686 F.3d 1348 (Fed. Cir. 2012).

CAFC or Supreme Court of the United States ("Supreme Court") to resolve this issue, and proffer some suggestions for what the scope of the safe harbor should be. Finally, effects of the current ambiguity of the safe harbor boundaries will be discussed.

I. Legal Context

In this section, the Hatch-Waxman Act and pertinent cases will be discussed in order to provide background so as to better understand the issues behind the controversy within the CAFC. While there is case law precedent for expanding the original reading of the Hatch-Waxman Act, courts that have expanded the Act have consistently done so by further interpreting the existing Act.

A. The Hatch-Waxman Act

The 1984 Hatch-Waxman (Drug Price Competition and Patent Term Restoration) Act was created to address several problems existent at that time with the patent and FDA processes.[5] During that period, the term of a patent was 17 years from the date of issue, but a patent owner could not begin to sell a patented pharmaceutical until after receiving FDA approval, generally after the patent had issued. Such FDA approval took years, sometimes consuming as much as half of the patent term. This left patent owners with relatively short patent terms in which to maximize commercial sales of a new drug before generic companies would have an opportunity to enter the market when the patent term expired.[6] On the other hand, generic companies desired to begin sales of a generic equivalent of the patented pharmaceutical as soon as possible after the

[5] BRUCE D. ABRAMSON, THE SECRET CIRCUIT: THE LITTLE KNOWN COURT WHERE THE RULES OF THE INFORMATION AGE UNFOLD 184 (Rowman and Littlefield Publishers 2007).
[6] Abramson, *supra* note 5, at 183.

patent term expired.[7] To do this, they too would need FDA approval, which required substantial clinical trial testing, therefore necessitating the use of the patented pharmaceutical: an act of infringement.[8]

The Hatch-Waxman Act offered succor to both patent owners and generic companies. The Act returned to patentees some of the patent term lost during the FDA approval process, thereby extending the patent term for a period beyond the original 17 years for patentees who had not received the benefit of the beginning of their patent term.[9] The Hatch-Waxman Act furthermore created the Abbreviated New Drug Application ("ANDA"), which allowed generic drug companies to substitute safety and efficiency testing from the patentee's application into their ANDA if the generic companies could show "bioequivalence."[10] This decreased the material necessary for a generic company to submit to receive approval, as compared to that of an original drug company under a New Drug Application ("NDA"), thereby streamlining the process.

Most notably, the Act allowed the generic company to make and use the patented product in order to show the requisite "bioequivalence" without constituting patent infringement, under what is known as the Hatch-Waxman safe harbor, codified under 35 U.S.C. §271(e).[11] Therefore, the generic company could begin the ANDA before the patentee's patent had expired and be ready to receive FDA approval and roll out generic equivalents of a just-expired patented pharmaceutical shortly after the expiration of the patent.

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[7] *Id.* at 183.
[8] *Id.*
[9] *Id.* at 184.
[10] *Id.*
[11] Abramson, *supra* note 5, at 184; 35 U.S.C. § 271(e) (2013).

However, under the Act, the very deed of submitting an ANDA could nevertheless trigger patent infringement litigation. When submitting an ANDA reading on patented subject matter, the generic applicant had to acknowledge the existence of the patent, but had two options as to how to proceed.[12] Under one option, the generic applicant could acknowledge that the patent(s) would expire and wait until that expiration date to receive FDA approval.[13] Alternatively, the generic applicant could claim that the patent was invalid or would not be infringed (and provide a detailed statement of the factual basis for this assertion) and request immediate FDA approval.[14] The latter was known as a Paragraph IV proceeding, and invited the patentee to bring an infringement suit within forty-five days of receiving notification of the generic applicant's assertion.[15] If no suit was brought, the applicant could potentially receive immediate FDA approval.[16] If a suit was initiated, the FDA could not approve the generic product for thirty months, or until the generic applicant had successfully defended himself, whichever occurred first.[17]

The Hatch-Waxman Act also impacts the average American consumer because it dictates the interactions of the FDA with generic drug companies and sets the stage for infringement suits between patentees and generic companies. These events in turn determine when generic equivalents of pharmaceuticals may enter the market, the access to which increases healthcare options and decreases healthcare costs.

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[12] Kenneth J. Burchfiel, *Biotechnology and the Federal Circuit,* 778 (2nd ed. 2010).
[13] *Id.;* 21 U.S.C. § 355(j)(2)(A)(vii).
[14] Burchfiel, *supra* note 12, at 778-79.
[15] *Id.* at 779.
[16] *Id.*
[17] *Paragraph Four Explained*, ParagraphFour.com, (2012) http://www.paragraphfour.com/explained/process.html (last visited Dec. 21, 2012).

B. Pertinent Case Law

In the most pertinent Supreme Court cases, the Court has shown a willingness to expand the boundaries of the safe harbor. However, the Court has also been mindful of the intent of the Hatch-Waxman Act. It has also shown caution and not expanded the bounds of the safe harbor so far as to obliterate the Act's goals of lengthening a patentee's valuable patent term and streamlining the lab-to-FDA approval process through which generic companies must go. With this in mind, a brief discussion of the three most related Supreme Court and CAFC cases on the Hatch-Waxman Act is in order.

In 1990, the Court ruled on the case of *Eli Lilly v. Medtronic*. Originally, it had been assumed that the Hatch-Waxman Act only applied to pharmaceuticals submitted to the FDA for approval. However, the Supreme Court found that the safe harbor protection against infringement actions was granted against the "patented invention."[18] There was therefore no provision limiting submissions before the FDA to just pharmaceuticals. Therefore, in *Eli Lilly*, the Court widened the material covered by the safe harbor to also include medical devices.[19]

More recently, the Supreme Court heard *Merck KGAA v. Integra Lifesciences* in 2005. The Court was tasked with determining whether experimental activity that was never used in an ANDA could still fall within the safe harbor provision.[20] Specifically, the Court looked at pre-clinical test results, which if not found to be within the safe harbor would constitute infringing activity.[21] Reasoning that pre-clinical testing is reasonably related to the development and submission of information under the applicable federal laws governing the regulation of drugs,

[18] *Eli Lilly & Co. v. Medtronic*, 496 U.S. 661, 665 (1990).
[19] *Eli Lilly*, 496 U.S. at 665.
[20] *Merck KGaA v. Integra Lifesciences I*, 545 U.S. 193, 195 (2005).
[21] *Id.*

the court ruled that pre-clinical testing is included in the protections of the Hatch-Waxman Act.[22] This even included pre-clinical testing that does not lead to an FDA submission. The Court recognized that at the time of pre-clinical testing, it is not foreseeable whether current and future testing results will be sufficiently successful to warrant an FDA application.[23]

The *Merck* decision led to controversy among patentees, scholars, and the scientific community, however. While a liberal interpretation of the Hatch-Waxman Act enabled pharmaceutical companies to conduct pioneering research in an inexpensive manner, a benefit which was ultimately passed on the consumer, concern about how far the scope of "reasonably related" went was expressed.[24] For example, if patentees could not protect the research tools and methods used in the laboratory and manufacturing stages to create a patented pharmaceutical from being appropriated by competitor generic companies and used to make bioequivalent drugs, then the incentive to patent these tools would be lost.[25] Instead, patentees would keep their research tools to the best of their abilities as trade secrets, effectively stifling development and technological growth.[26]

The CAFC offered some guidance on this matter two years later in *Proveris v. Innovasystems* when a panel of judges took the surprising turn of limiting the extent of the safe harbor.[27] The case asked the CAFC to look at the alleged infringements of a patented drug delivery device system, described as an accessory item to the drug for which FDA approval was

[22] *Id.* at 206.
[23] *Id.* at 207.
[24] Jonathan McPherson, *The Impact of the Hatch-Waxman Act's Safe Harbor Provision on Biomedical Research Tools after Merck KGaA v. Integra Lifesciences I, LTD,* 10 MICH. ST. U. J. MED. & L. 369 (Spr. 2006).
[25] *Id.*
[26] *Id.*
[27] Proveris Scientific v. Innovasystems, 536 F.3d 1256 (Fed. Cir. 2008).

being sought on an ANDA.[28] The court reasoned that the ability to receive a patent term adjustment went hand in hand with the scope of the Hatch-Waxman safe harbor.[29] Consequently, because the drug delivery device system was not eligible for a patent term adjustment, declaring its use within the bounds of the safe harbor in association with the preparation of an application for submission before the FDA was also not appropriate.[30] The Court did not address whether the patented drug delivery device system, or other research tools, would be considered "reasonably related" to the development and submission of information to the FDA.[31]

After *Proveris*, patentees, scholars, and the scientific community again reacted to the shifting perception of the law. One deficiency identified in the ruling was an inability to protect research tools that had not been labeled as research tools by the FDA.[32] It was also suggested that the CAFC's decision was influenced by the conduct of the alleged infringer, who did not merely make the device for its own use, but instead for sale to pharmaceutical companies.[33] Another criticism is that the CAFC may have narrowed the definition of "patented invention" as the Supreme Court had defined it in *Merck*. In the earlier case, the Supreme Court defined "patented invention" broadly under § 271(e)(1) to "include all inventions, not drug-related inventions alone."[34] However, in *Proveris*, the CAFC appeared to be tailoring that definition to only those inventions requiring FDA approval, thereby narrowing potential candidates for inclusion in the safe harbor.[35]

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[28] *Id.* at 1258.
[29] *Id.* at 1263.
[30] *Id.*
[31] *Proveris Scientific*, 536 F.3d at 1260.
[32] Adam Sibley, *The FDA safe Harbor Provision After Proveris*, 21 SYRACUSE SCI. & TECH. L. REP. 36, 38 (Fall 2009).
[33] *Id.* at 42.
[34] *Id.* at 45.
[35] *Id.* at 46.

Recognizing that broad definitions of research tools may be under or over inclusive, particularly in light of multiple uses of such tools, scholars have also suggested a case-by-case analysis by courts in order to determine whether unauthorized use of an invention would constitute a safe harbor exemption to infringement.[36]

II. Inconsistency within the CAFC

Although the Supreme Court and CAFC have held that the Hatch-Waxman safe harbor protects experimental activity prior to and related to applications for FDA approval, the CAFC's position on post-approval activity is far less clear. There is a need to define where the safe harbor boundary stops between experimental use and infringement in the marketplace.

A. ***Classen v. Biogen***

In 2011, a panel of judges on the CAFC heard the case of *Classen Immunotherapies v. Biogen IDEC*.[37] Although the case was primarily concerned with the patent eligibility of claims containing a mental step under 35 U.S.C. §101, the court also discussed whether experimental activity performed after market approval by the FDA could receive Hatch-Waxman safe harbor protection.[38] The claims in the litigation involved mental steps, sometimes coupled with an act; the court, for reasons outside of the scope of this paper, held some of the claims valid and infringed, and others invalid.[39]

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[36] Chenwei Wang, *In search of the Boundary of the Safe Harbor,* 19 FED. CIRCUIT B.J. 617, 627 (2010).
[37] *Classen*, *supra* note 3.
[38] *Id.* and Jason Rantanen, *Classen Immunotherapies v. Biogen: The Broad, Broad Scope of Statutory Subject Matter*, Patentlyo (August 31, 2011), http://www.patentlyo.com/patent/2011/08/classen-immunotherapies-v-biogen-the-broad-broad-scope-of-statutory-subject-matter.html (last visited Dec. 21, 2012).
[39] Rantanen, *supra* note 38.

However, as to the Hatch-Waxman Act, the Court firmly found, in an opinion written by Judge Newman and joined by Chief Judge Rader, that the Hatch-Waxman safe harbor only applied to pre-market experimental activity.[40] To support its findings, the court cited to the legislative history of the Hatch-Waxman Act to discern that the purpose of the safe harbor is only to protect activity in preparation of seeking FDA approval.[41] Specifically, the court cited to the House Report associated with the legislation, which stated 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 the drug would occur after expiration of the patent."[42] The court further emphasized from the legislative history that the information that can be developed under the Hatch-Waxman Act is "the type which is required to obtain approval of the drug."[43] The CAFC interpreted the Supreme Court's earlier *Eli Lilly* and *Merck* decisions as strictly applying to pre-clinical research where there is "a reasonable basis for believing that the experiments will produce "the types of information that are relevant to an IND [investigational new drug application] or NDA [new drug application].' "[44] Judges Newman and Chief Judge Rader firmly asserted that the Hatch-Waxman safe harbor would not and could not apply to activities taking place after market approval by the FDA.

Judge Moore dissented, however, and advanced a theory that Hatch-Waxman safe harbor did not merely apply to pre-approval activity.[45] In her dissent, Judge Moore took particular note of the discussion of 35 U.S.C. §271(e) in *Merck* in which the Court stated that "the statutory text

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[40] *Classen*, *supra* note 3, at 1070.
[41] *Id.*
[42] *Classen*, *supra* note 3, at 1071, quoting H.R. Rep. No. 98-857, pt. 1, at 15, 1984 U.S.C.C.A.N. 2647, 2648 (1984).
[43] *Classen*, *supra* note 3, at 1071 (quoting H.R. REP. No. 98-857, pt. 1, at 45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2678.
[44] *Classen*, *supra* note 3, at 1072 (quoting *Merck, supra* note 20).
[45] *Classen*, *supra* note 3, at 1083 (Moore, dissenting).

makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process" and that the §271(e) exemption "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA [Food, Drug, and Cosmetic Act]."[46] Judge Moore argued that any activity, regardless of research stage, may be eligible for protection under the Hatch-Waxman safe harbor if reasonably related to submitting any information before the FDCA, including information regarding post-approval uses.[47]

B. *Momenta v. Amphastar*

Only a year later, a slightly different panel of judges: Judge Dyk, Judge Moore and Chief Judge Rader, heard *Momenta Pharmaceuticals v. Amphastar Pharmaceuticals*. The difference of one judge led to startlingly different conclusion in the *Momenta* case as compared with *Classen* with respect to the Hatch-Waxman safe harbor. After Amphastar received its FDA approval in Autumn 2011, Momenta, holder of method patents for manufacturing processes of a generic version of the low molecular weight heparin Lovenox, or enoxaparin, promptly brought a patent infringement lawsuit against Amphastar.[48]

Although Momenta was not the patentee of the original enoxaparin pharmaceutical, the patent for which had been held by Sanofi-Aventis, Momenta holds method patents on methods of making enoxaparin and was the first generic drug company to successfully receive FDA approval for a generic version of enoxaparin.[49] In its complaint, Momenta specifically alleged

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[46] *Classen*, *supra* note 3, at 1083 (quoting *Merck*, *supra* note 20).
[47] *Classen*, *supra* note 3, at 1083.
[48] *Momenta, Sandoz file patent suit against Amphastar and Watson over Enoxaparin Sodium Injection*, NEWS-MEDICAL (Sept. 23, 2011) http://www.news-medical.net/news/20110923/Momenta-Sandoz-file-patent-suit-against-Amphastar-and-Watson-over-Enoxaparin-Sodium-Injection.aspx.
[49] *Momenta*, *supra* note 4, at 1351.

infringement of Momenta patents 7,790,466 and 7,575,886 on methods of making and analyzing generic enoxaparin.[50] Momenta believed that Amphastar had used Momenta's methods in order to prepare enoxaparin samples for testing in preparation for bringing the drug to market after Amphastar had received FDA approval for a generic version of enoxaparin.[51]Amphastar, however, argued that its post-approval testing fell with the scope of the Hatch-Waxman safe harbor.[52]

Initially, the District Court of Massachusetts granted Momenta a preliminary injunction, stopping the sales of Amphastar's generic enoxaparin. However, Amphastar appealed to the CAFC, whose majority viewed the injunction skeptically.[53] The CAFC vacated and remanded the injunction to the district court, with strict language discouraging the injunction.[54] The CAFC stated that as the party seeking the injunction, Momenta bore the burden of establishing that it was entitled to the "extraordinary relief" of the injunction, and had failed to meet this burden.[55]

Defending its activities, Amphastar asserted that its actions fell within the Hatch-Waxman safe harbor, a defense originally rejected by the District Court.[56] However, the CAFC majority agreed with Amphastar, taking a broad interpretation to the activities covered within the safe harbor. In an opinion written by Judge Moore, largely consistent with her dissent in *Classen*, the court found that the safe harbor could include post-FDA-approval activities, because the Hatch-Waxman statute did not specify under what Federal laws information need be

[50] *Momenta, Sandoz file patent suit*, *supra* note 48.
[51] *Momenta, supra* note 4, at 1352.
[52] *Id.*
[53] Kevin E. Noonan, *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc. (Fed. Cir. 2012),* PATENT DOCS (Aug. 9, 2012), http://www.patentdocs.org/2012/08/momenta-pharmaceuticals-inc-v-amphastar-pharmaceuticals-inc-fed-cir-2012.html (last visited Dec. 20 2012).
[54] Noonan, *supra* note 53.
[55] Noonan, *supra* note 53.
[56] *Id.*

submitted, and as such, activity need not be limited to that required for FDA approval.[57] Accordingly, the CAFC ruled that Amphastar's use of Momenta's processes, although after FDA approval, was within the bounds of the Hatch-Waxman safe harbor.[58] Therefore, Amphastar's defense was valid.[59]

Chief Judge Rader took great umbrage with the court's decision and in his dissent argued that the court had failed to follow its own precedent from *Classen*, creating substantial inconsistency within the circuit.[60] He argued that because Momenta's patented processes had been used to test Amphastar's samples for the market after Amphastar's FDA approval, Amphastar's activity should not fall into the Hatch-Waxman safe harbor.[61]

Following the decision of the CAFC panel, Momenta petitioned the Supreme Court of the United States for *writ of certiorari*, but the petition was denied in June 2013.[62] In a related case, in light of outcomes in the Amphastar litigation, Momenta also failed in July 2013 to assert its '886 patent against Teva Pharmaceuticals USA.[63]

C. Post FDA Approval Controversy

Between the CAFC's decisions in *Classen* and *Momenta*, an inconsistency has presented itself concerning what activity is protected within the bounds of the Hatch-Waxman safe harbor. Judge Newman, joined by Chief Judge Rader, held in *Classen* that activity conducted after FDA

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[57] *Momenta*, 659 F.3d at 1355.
[58] Noonan, *supra* note 53.
[59] *Id.*
[60] Eric W. Guttag, *Momenta Pharmaceuticals: The Hatch-Waxman "Safe Harbor" Widens to Include Post-FDA Approval Activity*, IP WATCHDOG (Aug. 7, 2012, 10:27 am), http://www.ipwatchdog.com/2012/08/07/momenta-pharmaceuticals-the-hatch-waxman-safe-harbor-widens-to-include-post-fda-approval-activity/id=27191/ (last visited Dec. 20, 2012).
[61] *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d at 1362 (Rader, C.J., dissenting).
[62] *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 133 S.Ct. 2854 (2013).
[63] *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 2013 WL 3893417, *2 (Mass. Dist. Ct. July 19, 2013).

market approval is clearly not within the safe harbor. However, Judge Moore, joined by Judge Dyk, was of the opinion in *Momenta* that activity is within the bounds of the safe harbor if the activity is reasonably related to the development and submission of information before the FDA, regardless of whether that activity is conducted before and as part of the FDA approval process, or even after approval.

When presented with a judicial framework which does not have an FDA approval cut-off for activity within the safe harbor, it is further unclear when activity ceases to be reasonably related to submissions before the FDA. For example, would activity necessary to meet certain federal formalities be reasonably related? Would activity conducted prior to FDA approval but having little bearing on the approval process be considered reasonably related? Under the current *Momenta* decision, district courts now not only have contradictory instructions, but also have only vague guidelines for how to address potentially infringing activity.

Furthermore, as Chief Judge Rader argued in his dissent in *Momenta*, the majority failed to appreciate that the language of 35 U.S.C. §271(e)(1) contains the limitation "solely," which limits the purpose of the activities that can be admitted into the safe harbor.[64] Under the Chief Judge's construction, an activity that has another purpose, such as marketing, and is not "solely for uses reasonably related to the development and submission of information under a Federal law," does not qualify under the safe harbor.[65]

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[64] *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d at 1374 (Rader, C.J., dissenting).
[65] 35 U.S.C. § 271(e)(1) (2010); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d at 1374 (Rader, C.J., dissenting).

III. Judiciary Should Resolve Scope of the Safe Harbor

In September 2012, Momenta petitioned for a rehearing *en banc* in part to resolve the inconsistencies that the court had seemingly created in the Hatch-Waxman safe harbor law.[66] Classen Immunotherapies filed an *amicus curiae* brief in support of the petition because Classen also wished to see the law resolved.[67] Classen had petitioned the Supreme Court on the issue, but was denied *certiorari* and the case was not heard.[68] Classen was also concerned that until the coverage of the Hatch-Waxman safe harbor was resolved, its ability to litigate its patents would be negatively impacted.[69] Momenta and Classen are correct; there is a need for resolution of this matter.

The CAFC should accept the petition from Momenta to rehear the case *en banc* in order to provide a more definitive resolution of the question as to what activity is covered within the Hatch-Waxman safe harbor. If, for some reason, the court refuses to rehear *Momenta en banc*, a need will still exist for the law to be settled in this area. Accordingly, if the CAFC does not agree to hear *Momenta*, the court should nonetheless agree to hear a similar case *en banc* to resolve this matter.

However, given the importance of this issue, a timely resolution of the apparent inconsistency in the Hatch-Waxman safe harbor law is needed. Given that *Momenta* presents a clean issue that if resolved either for or against widening the Hatch-Waxman safe harbor would present a clear precedent for future cases in the lower courts, the *Momenta* case would be an

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[66] Petition for Rehearing En Banc, Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348 (2012) (No. 2012-1062), 2012 WL 4662298.
[67] Brief of Amicus Curiae Classen Immunotherapies, Inc. in Support of the Petition for Rehearing En Banc, Momenta v. Amphastar, 686 F.3d 1348 (2012) (No. 2012-1062) 2012 WL 4762489.
[68] *Id.*
[69] Brief of Amicus Curiae Classen Immunotherapies, *supra* note 67.

appropriate vehicle for an *en banc* rehearing. Moreover, since similar cases are likely to be seen in increasing numbers in district courts going forward, there is a need for this issue to be resolved forthwith.

In view of the 2-1 split decisions in the *Momenta* and *Classen* cases, this issue is ripe to be heard by the full panel CAFC judges. Between the two cases, it appears that Judge Newman and Chief Judge Rader favor an exclusively pre-approval based interpretation of the Hatch-Waxman safe harbor, which is derived from legislative intent.[70] Contrastingly, Judge Dyk and Judge Moore have advocated for a "reasonably related to approval" interpretation. This interpretation of the Hatch-Waxman safe harbor is based on a textual approach.[71] The opinions of the other sitting judges are as of yet unknown with respect to this matter. Accordingly, given the apparent deadlock in opinion, now would be an appropriate time for the full panel to weigh-in on this matter.

Moreover, a full bench opinion would also sufficiently crystalize the issue were it to appear before the Supreme Court as a second petition in *Momenta* or embodied in a separate case. Although parties can appeal directly to the Supreme Court from a panel decision by the CAFC, as can be inferred by the Supreme Court's denial of *certiorari* in *Momenta*, the Supreme Court is unlikely to accept appeals that have not first been reviewed by the full panel, but may be persuaded to do so after a full review. The CAFC is also itself more likely to accept cases for an *en banc* hearing where the panel originally hearing the matter was split.

Although currently the Supreme Court has denied Momenta *certiorari* and the CAFC has remained further silent, continued action before the CAFC and the Supreme Court is urged. The issue of whether post-FDA approval activity constitutes infringement, a question which has

[70] *Classen, supra* note 3; *Momenta, supra* note 4, (Rader, dissenting).
[71] *Classen, supra* note 3 (Moore, dissenting); *Momenta, supra* note 4.

profound implications for the pharmaceutical industry, is of sufficient importance that a full bench hearing before the CAFC is warranted to clarify this issue. Additionally, if further clarification remains necessary, the Supreme Court should then grant *certiorari* to timely resolve this matter.

How the Supreme Court would decide an appeal from *Momenta* would be another question. The *Eli Lilly* and *Merck* decisions suggest deference for a broad interpretation of the Hatch-Waxman safe harbor. Even so, the Supreme Court never showed an interest hearing *Proveris* or granting *certiorari* on a similar case, which would suggest that the Supreme Court favors certain limits on the extent of the safe harbor. Certainly, the Supreme Court has an interest in fostering innovation and protecting the property rights of patentees; it also desires to assist the interests of the health care system by removing obstacles in the path of generic pharmaceutical companies as they move their products to market. However, with regard to patent cases, the Supreme Court has rendered surprising decisions at times.

Alternatively, the Legislative Branch could also provide guidance as to what exceptions to infringement the Hatch-Waxman safe harbor should provide to generic pharmaceutical companies. Even though the Patent Act has recently undergone major revisions in the form of the America Invents Act (AIA), no changes were made to infringement statute 35 U.S.C. §271.[72] It is unclear whether the lack of changes to the Hatch-Waxman safe harbor exception in the AIA is intended as a tacit concurrence on the present wording of the law, or a mere oversight by Congress to address the need for specific rules in this area governing where the infringement line resides. However, technical amendments are still being made to the AIA and will most likely continue to be made for some time into the future as courts and the U.S. Patent and Trademark

[72] 35 U.S.C. § 271 (2013).

Office adjust to the new law. Accordingly, there is still time for legislators to offer resolution. In fact, Senator Hatch and Representative Waxman should both be sufficiently concerned by the unraveling of the legislation they sponsored to be motivated to enact measures clarifying the intent of the Act, thereby making further judicial intervention unnecessary.

IV. Where the Safe Harbor Boundary Should Reside

The CAFC should establish a boundary for the safe harbor so as to protect experimental work prior to FDA approval, while excluding from protection all activity conducted thereafter that is necessary for FDA approval. This arrangement would protect companies and other entities interested in developing generic pharmaceuticals, while simultaneously protecting the market interests of patentees during the terms of their patents.

Entities that experiment with a patented pharmaceutical need to be able to do so without fear of a patent infringement suit. Such entities should include prospective generic drug companies, as well as universities that are merely interested in studying the operation of the pharmaceutical, but which are most likely not interested in direct commercialization. Under *Merck*, even preliminary experimentation that may never lead to an ANDA is protected within the Hatch-Waxman safe harbor, so long as there is a reasonable expectation that such experimentation could lead to an ANDA.[73] However, under *Proveris*, research tools are specifically excluded from the safe harbor.[74] This allows a patentee of the tool to receive the full benefit of the patent term and creates an incentive to develop such tools without fear that they will be appropriated by others for "experimental use." With this foundational case law, there

[73] *Mereck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 195 92005).*supra* note 20.
[74] *Proveris Scientific Corp. v. Innovasystems,* Inc., 536 F. 3d 1256 (Fed. Cir. 2008).

appears to be a directive from the courts to sponsor research and innovation. This directive would be frustrated if the infringement status of post-FDA approval activity is not made clear.

Accordingly, the CAFC should establish precedent so that the Hatch-Waxman safe harbor does not touch upon any activity conducted subsequent to activities necessary for FDA approval. As Chief Judge Rader explained in his dissent in *Momenta*, when legislators wrote the Hatch-Waxman Act, their purpose was to resolve inadequacies in the old law: seemingly truncated patent terms for patentees and a tedious FDA approval process for generic companies that could only begin after the expiration of the original patent.[75] It was never the legislators' intent to give generic companies entrance into a patentee's market while a patent was still in force.

Allowing a generic company to reach beyond FDA approval and engage in subsequent activities constitutes a taking for which the government provides tacit approval. Even if a generic company did not being selling a FDA approved product until after the patent has expired, the generic company would still have received a substantial head start on bringing the generic to market. After receiving FDA approval for a new drug or product, the original patentee must blaze the path of the drug to the marketplace. Considerable resources, including capital and time from the patent term, are devoted to determining best manufacturing processes, making inroads with distributers, and advertising the new drug to healthcare professionals and the general public. The patentee must work to garner the reputation of the new drug, carve out a market, and determine lucrative off label uses for the drug. Evidently, there is significant lead time between FDA approval and actual market entry. While this time will be shorter for a generic company

[75] *Momenta Pharms. Inc. v. Amphastar Pharms, Inc.*, 686 F. 3d 1348, 1364 (Fed. Cir. 2012) (Rader, R., dissenting); Abramson, *supra* note 5, at 184.

that has the advantage of the patentee's drug's reputation, it should not be non-existent. If a generic company is permitted to engage in post-approval activities such as manufacturing while the patent is still in force, it bypasses this lead time, which is an unjust taking from the patentee.

As Chief Judge Rader indicated in his dissent, quoting from the legislative history:

> The purpose of 271(e)(1) and (2) is to establish that **experimentation** with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of **experimentation** is infringement. In Roche Products, Inc. v. Bolar Pharmaceutical Co., [] the Court of Appeals for the Federal Circuit held that the **experimental use** of a drug product prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though **the only purpose of the experiments is to seek FDA approval** for the commercial sale of the drug after the patent expires. It is the Committee's view that **experimental activity** does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.[76]

Chief Judge Rader further indicated from the legislative history:

> Section 202 [of the bill] does not authorize any activity which would deprive the patent owner of the sale of a single tablet during the life of a valid patent. In fact, the limited testing activity required to obtain FDA approval of a generic drug would not normally result in the use of even a single generic tablet for its therapeutic purpose during the life of a valid patent.[77]

As the Chief Judge indicated from the legislative history, the legislators understood at the time the Hatch-Waxman Act was being put together that the safe harbor would be carving out some

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[76] *Momenta Pharms. Inc. v. Amphastar Pharms, Inc.*, 686 F. 3d 1348, 1364 (Fed. Cir. 2012)(Rader, R., dissenting);(quoting H.R.Rep. No. 98–857, pt. 1, at 45–46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678–2679 (emphases added).

[77] *Momenta Pharms. Inc.*, 686 F.3d at 1364 (Rader, R., dissenting) (quoting *Innovation and Patent Law Reform: Hearing on H.R. 3605 Before the Subcomm. On Courts, Civil Liberties and the Admin. Of Justice of the H. Comm. On the Judiciary*, 98th Cong. 926 (1984) (memorandum of Alfred B. Engelberg, Patent Counsel, Generic Pharmaceutical Industry Association) (emphasis added)).

very specific exceptions for experimentation to seek FDA approval for commercial sales after patent expiration. It was never their intent to grant generic companies the ability to build upon a patentee's successful market development while the patentee still held a patent, thereby siphoning sales from the patentee.

Chief Judge Rader also took particular issue with the failure of the majority in *Momenta* to address the phrase "*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" (emphasis added).[78] The Chief Judge found the word "solely" to be key. Under Rader's construction of the phrase, activity must be "solely" for development and submission before the FDA. Further development, such as that leading to the market, is impermissible under this statute.[79] This results in a narrower amount of information which may be protected within the safe harbor. It is a long held principle that it is necessary to consider all terms when construing a statute. It appears that the CAFC panel majority failed to give adequate weight to the term "solely" and therefore construed the Hatch-Waxman safe harbor too broadly.

Momenta also brought to the forefront the need to address the process patent protection within the Hatch-Waxman safe harbor. If a generic company is permitted to use a process after FDA approval in order to make a product ready for market in such a way that the patented invention has been used, then under traditional construction, patent infringement has occurred. Yet, the majority in *Momenta* believed this is not the case and would effectively permit such activity to continue for the full term of the patent. Patented processes are certainly statutory subject matter under the Patent Act to the same extent as patented compounds, and should

[78] *Momenta Pharms. Inc.*, 686 F.3d at 1374 (Rader, R., dissenting); 35 U.S.C.A. § 271(e)(1) (2010).
[79] *Momenta Pharms. Inc.*, 686 F.3d at 1374 (Rader, R., dissenting).

therefore be afforded the same degree of protection and recognition under the Hatch-Waxman Act.[80]

However, while a literal interpretation of the Hatch-Waxman Act may indeed suggest that any activity required by a federal law should fall under the safe harbor, as was suggested by the majority in *Momenta*, this would open the safe harbor to potential abuses. As federal regulations govern and require many acts, even those far removed from the manufacture, use, or sale of drugs, it would become increasingly unclear which post-FDA approval activities were within the safe harbor and which were not. Therefore, the safe harbor must be construed to *solely* include pre-FDA approval activities within the scope of the harbor, as is consistent with the intent of the drafter and how the Act has been interpreted up until this point in time.

V. Impact of Inconsistent Interpretations of the Law

As provided in the U.S. Constitution, Congress has the power "To promote the progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their Writings and Discoveries."[81] Accordingly, the term of a patent grant is meant to run for only a limited period of time. The current state of the law is contradictory to this, as it does not give patentees the full term to which they are entitled and creates uncertainty such that generic companies may be deterred from entering the market. It was certainly not the intent of 35 U.S.C. § 271(e)(1) to curtail a patent grant to a patentee once a generic company had achieved FDA approval.[82] Such increased uncertainty in the law is detrimental to all stakeholders involved.

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[80] 35 U.S.C. § 101.
[81] U.S. Constitution, Art. I, Section 8, ¶8.
[82] *Momenta Pharms. Inc.*, 686 F.3d at 1374 (Rader, R., dissenting).

Under pre-*Momenta* interpretations of the Hatch-Waxman safe harbor, patentees had a high degree of certainty that their patent monopoly would end only when their patent expired, and that their market monopoly would subsequently come to an end when a generic competitor achieved FDA approval.[83] If the generic competitor has already completed the requirements for FDA approval during the patent term, the patentee would be aware of this, and could prepare itself for market loss once its patent expires.[84] However, under *Momenta's* interpretation of the Hatch-Waxman safe harbor, it is far less clear what activities the generic competitor can engage in while the patent is still in force. For example, this may allow the competitor to potentially break into the patentee's market during the patent term. Consequently, patentees will not have a clear understanding of when their patent monopolies will effectively expire or what activities constitute infringement of that monopoly. This increased uncertainty trickles into other areas, including business uncertainty, because the inability to assess a patent can have dire consequences in terms of lost revenue.[85] By contrast, corporations that hold patents and their shareholders desire to minimize risk and shift capital to fields where the law and patent rights are less uncertain.[86]

Generic companies are also at a disadvantage by not having a clear understanding of what activities are and are not permissible under the Hatch-Waxman Act. Preparing to bring a generic drug to market requires resources, including funding, preparation of manufacturing facilities, and

[83] Abramson, *supra* note 5, at 184.
[84] Abramson, *supra* note 5, at 184.
[85] Roger D. Blair and Thomas F. Cotter, *Rethinking Patent Damages*, 10 TEX. INTELL. PROP. L.J. 1, 7-9 (Fall 2001).
[86] Douglas O. Edwards, *An Unfortunate "Tail": Reconsidering Risk Management Incentives After the Financial Crisis of 2007-2009*, 81 U. COLO. L. REV. 247, 247 (Winter 2010).

clinical testing mandated by the FDA.[87] If any of these activities may be construed as an infringement, investors and shareholders may not be willing to assume the heightened risk that such uncertainty creates. Moreover, as a drug patent nears the end of its term, there is often more than one generic company circling around the patented invention. If some generic companies develop the patented pharmaceutical significantly past the point of FDA approval whereas others do not, it will provide an unfair advantage to some companies when the patent expires and generic companies are clearly free to enter the market.

Furthermore, consumers and the healthcare system face a twofold disadvantage. First, prices are likely to be higher from companies insulating themselves from business uncertainty in the wake of a poorly understood Hatch-Waxman safe harbor.[88] Second, the availability and variety of generic products requiring FDA approval are likely to be reduced through less willing competition on the market due to the greater potential for infringement suits and deterioration of patent rights.[89]

Conclusion

The Patent Act grants for a limited time to a patentee a right to exclude all others from an invention, with specific exceptions. One of those exceptions is the Hatch-Waxman safe harbor, which allows for experimental use prior to and as a part of the submissions process before the FDA under 35 U.S.C. § 271(e)(1). However, differing opinions have arisen among the judges of the CAFC as to the extent of the safe harbor as it pertains to post-approval activities. There is a

[87] *How to Market Your Device*, FDA, http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/default.htm (last updated Sept. 25, 2013).
[88] Eric L. Talley, *On Uncertainty, Ambiguity, and Contractual Conditions,* 34 DEL. J. CORP. L. 755, 760 (2009).
[89] Edwards, *supra* note 86; Abramson, *supra* note 5, at 184.

considerable need to know among patentees, generic drug companies, and the medical industry in general what post FDA approval activities constitute infringement. The willingness of capital markets to provide financial support to bring new drugs to market and very shape of the patentee-generic relationship are at stake.

The balance struck by the Hatch-Waxman (Drug Price Competition and Patent Term Restoration) Act should be maintained. Patentees should receive the full benefit of their patent term with a minimum of interference from competitor generic companies. Conversely, once that patent term has expired *and only* once that patent term has expired, generic drug companies should be able to take full advantage of the freedom opened up by the lack of patent restriction. However, generic companies should not be able to interfere in the patentee's market while the patent is still in force or attempt to gain a comparative advantage with respect to other generic companies. Such conduct is a disincentive to the market and impacts all parties involved, including consumers. Likewise, such conduct discourages innovation and the creation of new pharmaceuticals. The original intent of the Hatch-Waxman Act must be respected.