

Patent Infringement and Experimental Use Under the Hatch-Waxman Act: Current Issues

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Summary

Concerns over the availability of affordable health care have focused national attention upon patents and other intellectual property rights awarded to pharmaceutical firms. Legislation that was introduced before, but not enacted by, the 112th Congress proposed amendments to the Hatch-Waxman Act, legislation dating from 1984 that governs intellectual property rights in pharmaceuticals and other regulated products. Recent rulings from the federal judiciary regarding the Hatch-Waxman Act may be pertinent to future congressional consideration of that statute. Both the judicial holdings, as well as possible legislative changes to the Hatch-Waxman Act, potentially affect the availability of both brand-name and generic drugs in the United States.

The Hatch-Waxman Act includes two core provisions that impact the enforcement of patent rights by brand-name firms against generic pharmaceutical companies. 35 U.S.C. §271(e)(1) creates a statutory "safe harbor" that exempts firms from claims of patent infringement based on clinical trials and other acts reasonably related to seeking marketing approval from the Food and Drug Administration (FDA). The explicit wording of that statute does not preclude activities that occur after the receipt of FDA marketing approval from the "safe harbor." Two recent opinions from the U.S. Court of Appeals for the Federal Circuit are arguably in tension over whether post-approval acts are exempted from infringement, however.

A second provision, 35 U.S.C. §271(e)(2), allows a brand-name drug company to enforce its patents against a potential generic competitor at such time that the generic firm files an application—a so-called Abbreviated New Drug Application (ANDA)—with the FDA seeking marketing approval. Although courts have stated that this litigation may only be based upon patents identified to the FDA and listed in the so-called "Orange Book," the express wording of the statute does not appear to impose this requirement. This issue has yet to be conclusively resolved in the courts.

Should Congress conclude that the current situation with respect to 35 U.S.C. §271(e) is satisfactory, no action need be taken. If Congress wishes to intervene, however, then some options present themselves. Congress could stipulate whether 35 U.S.C. §271(e)(1) applies to acts that occur following the award of FDA marketing approval or not. Congress could also explicitly state whether 35 U.S.C. §271(e)(2) establishes a cause of action for infringement of patents that have not been listed in the Orange Book.

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Background

The high cost and availability of health care in the United States have focused attention upon patents and other intellectual property rights available to pharmaceutical firms. Of particular moment to this discussion is the Hatch-Waxman Act, legislation that governs intellectual property rights with respect to pharmaceuticals and other regulated products. More formally known as the Drug Price Competition and Patent Term Restoration Act of 1984,[1] this legislation is widely regarding as having a strong impact upon the availability of both brand-name and generic pharmaceuticals in the United States.[2]

The Hatch-Waxman Act includes two core provisions addressing the enforcement of pharmaceutical patents. The first of those, 35 U.S.C. §271(e)(1), creates a statutory "safe harbor" that exempts firms from claims of patent infringement based on clinical trials and other acts reasonably related to seeking marketing approval from the Food and Drug Administration (FDA).[3] A second provision, 35 U.S.C. §271(e)(2), allows a brand-name drug company to enforce its patents against a potential generic competitor at such time that the generic firm files an application—a so-called Abbreviated New Drug Application (ANDA)—with the FDA seeking marketing approval. In support of the brand-name firm's intellectual property rights, the FDA publishes information pertaining to patents that the brand-name firm identifies to the agency.[4] If the generic firm does not agree to wait until these patents expire before marketing its product, then the brand-name firm may commence patent infringement litigation immediately.[5]

Recent judicial developments have involved both provisions. Two recent judgments from the U.S. Court of Appeals for the Federal Circuit are arguably in tension as to whether the statutory safe harbor is limited to activities performed prior to the award of FDA approval.[6] Because 35 U.S.C. §271(e)(1) does not expressly restrict its scope to premarketing approval efforts,[7] these holdings have been the subject of considerable discussion. As well, brand-name firms have attempted to assert patents against generic firms that they have not explicitly identified to the FDA. Although the Supreme Court has suggested that such identification is a predicate for litigation,[8] 35 U.S.C.

[1] P.L. 84-417, 98 Stat. 1585 (1984).

[2] See, e.g., Michael R. Herman, "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation," 111 *Columbia Law Review* (2011), 1788.

[3] See Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005).

[4] U.S. Department of Health and Human Services, Food and Drug Administration, Electronic Orange Book, Center for Drug Evaluation and Research, "Approved Drug Products with Therapeutic Evaluations" (available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm).

[5] 21 U.S.C. §355(j)(5)(B)(iii).

[6] Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc., 686 F.3d 1348 (Fed. Cir. 2012); Classen Immunotherapies, Inc. v. Biogen Idec, 659 F.3d 1057 (Fed. Cir. 2011).

[7] 35 U.S.C. §271(e)(1) provides in pertinent part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within 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.

[8] Eli Lilly v. Medtronic, 496 U.S. 661, 678 (1990) ("That is what is achieved by §271(e)(2)-the creation of a highly artificial act of infringement that consists of submitting an ANDA ... containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.").

§271(e)(2) does not expressly state as much.[9] The courts have yet to rule definitively on this point.

This report will discuss current issues with respect to the patent infringement provisions of the Hatch-Waxman Act. The report begins by laying out the basics of the Hatch-Waxman patent dispute resolution system. It then describes the recent holdings of the Court of Appeals for the Federal Circuit in *Classen Immunotherapies LLC v. Biogen Idec*[10] and *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc*.,[11] concerning the applicability of the statutory safe harbor to activities that occur subsequent to FDA approval. Next, the report considers judicial developments regarding the patent infringement provision of the Hatch-Waxman Act. This report closes with a review of pertinent legislative issues.

Introduction to the Hatch-Waxman Act

The Hatch-Waxman Act brings together two previously distinct legal regimes, the patent law and the food and drug law. Under the latter regime, the sponsor of a new drug must demonstrate that the product is safe and effective in order to obtain FDA approval. This showing typically requires the drug's sponsor to conduct both preclinical and clinical investigations.[12] In deciding whether to issue marketing approval or not, the FDA evaluates the test data that the sponsor submits in a so-called New Drug Application (NDA).

Prior to the enactment of the Hatch-Waxman Act, the federal food and drug law contained no separate provisions addressing marketing approval for generic versions of drugs that had previously been approved by the FDA.[13] The result was that a would-be generic drug manufacturer had to file its own NDA in order to sell its product.[14] Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug by submitting a so-called paper NDA. Because these sorts of studies were not available for all drugs, however, not all generic firms could file a so-called paper NDA.[15] Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval.[16] Consequently, some generic manufacturers were

[9] 35 U.S.C. §271(e)(2) provides in pertinent part:

> It shall be an act of infringement to submit ... an application ... for a drug ... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

[10] 659 F.3d 1057 (Fed. Cir. 2011).

[11] 686 F.3d 1348 (Fed. Cir. 2012)

[12] See G. Lee Skillington & Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law and Business* (2003), 1.

[13] See Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389.

[14] See James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984," 34 *Catholic University Law Review* (1986), 433.

[15] See Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interest or Survival of the Fittest?," 57 *Food & Drug Law Journal* (2002), 247.

[16] Id.

forced to prove once more that a particular drug was safe and effective, even though their products were chemically identical to those of previously approved pharmaceuticals.

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process.[17] These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[18]

In response to these concerns, Congress enacted the Hatch-Waxman Act, a statute that has been described as a "complex and multifaceted compromise between innovative and generic pharmaceutical companies."[19] Its provisions include a new statutory pathway, the Abbreviated New Drug Application or ANDA, which expedites the marketing approval process for generic drugs. An ANDA allows a generic applicant to obtain marketing approval by demonstrating that the proposed product is bioequivalent to an approved pioneer drug. Unlike brand-name firms, generic drug companies are not required to undertake costly and time-consuming clinical trials in order to demonstrate the safety and effectiveness of their products.

Patent Infringement Dispute Resolution

When drafting the Hatch-Waxman Act, Congress recognized that brand-name pharmaceutical firms may be the proprietors of one or more patents directed towards their products. These patents might be infringed by a product described by a generic firm's ANDA in the event that product is approved by the FDA and sold in the marketplace. The Hatch-Waxman Act therefore established special procedures for resolving patent disputes in connection with applications for marketing generic drugs. Reflecting its compromise nature, the legislation both provides an exemption for patent infringement (for FDA regulatory compliance activities) and creates a new infringing act (the filing of certain ANDAs by generic firms).

First, the Hatch-Waxman Act established a statutory research exemption to patent infringement. 35 U.S.C. §271(e)(1) applies "solely to 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." The Supreme Court has observed that although "the contours of this provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process."[20] This statutory "safe harbor" most commonly operates in favor of generic firms who wish to perform activities, including bioequivalence studies, prior to filing their ANDAs.

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[17] See, e.g., Justina A. Molzon, "The Generic Drug Approval Process," 5 *Journal of Pharmacy & Law* (1996), 275 ("The Act streamlined the approval process by eliminating the need for [generic drug] sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product.").

[18] See Jonathan M. Lave, "Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?," 64 *University of Pittsburgh Law Review* (2002), 201 ("Hatch-Waxman has also increased the generic drug share of prescription drug volume by almost 130% since its enactment in 1984. Indeed, nearly 100% of the top selling drugs with expired patents have generic versions available today versus only 35% in 1983.").

[19] Natalie M. Derzko, "A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?," 44 *IDEA: Journal of Law and Technology* (2003), 1.

[20] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

The Hatch-Waxman also establishes a new cause of action for infringement. 35 U.S.C. §271(e)(2) states that each NDA applicant "shall file" a list of patents that the applicant believes would be infringed if a generic drug were marketed prior to the expiration of these patents.[21] The FDA then lists these patents in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is more commonly known as the "Orange Book."[22] Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market. Four possibilities exist:

> (1) that the brand-name firm has not filed any patent information with respect to that drug;
>
> (2) that the patent has already expired;
>
> (3) that the generic company agrees not to market until the date on which the patent will expire; or
>
> (4) that the patent is invalid or will not be infringed by the manufacture, use or sale of the drug for which the ANDA is submitted.[23]

These certifications are respectively termed paragraph I, II, III, and IV certifications.[24] An ANDA application certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[25] A generic firm that files an ANDA including a paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[26]

The filing of an ANDA application with a paragraph IV certification constitutes a "somewhat artificial" act of patent infringement under the Hatch-Waxman Act.[27] The statute requires the generic applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification.[28] The patent owner may then commence patent infringement litigation against that applicant.

The Safe Harbor Provision

The scope of 35 U.S.C. §271(e)(1) was recently the subject of judicial consideration. By its own terms, this statute does not restrict its infringement safe harbor to activities performed prior to the award of marketing approval by the FDA.[29] In the August 31, 2011, panel opinion in *Classen*

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[21] 21 U.S.C. §355(b)(1).

[22] See, e.g., Jacob S. Wharton, "'Orange Book' Listing of Patents Under the Hatch-Waxman Act," 47 *St. Louis University Law Journal* (2003), 1027.

[23] 21 U.S.C. §355(j)(2)(A)(vii).

[24] See Douglas A. Robinson, "Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now In Exchange for Less Pharmaceutical Innovation Later?," 81 *Washington University Law Quarterly* (2003), 829.

[25] 21 U.S.C. §355(j)(5)(B)(i).

[26] 21 U.S.C. §355(j)(5)(B)(ii).

[27] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 1047 (1990).

[28] 21 U.S.C. §355(j)(2)(B)(i).

[29] 35 U.S.C. §271(e)(1) provides in pertinent part:

(continued...)

Immunotherapies LLC v. Biogen Idec,[30] a three-judge panel of the Federal Circuit nonetheless concluded that this statute was "directed to premarketing approval of generic counterparts before patent expiration."[31] In view of this holding, activities not associated with the preparation of an NDA or ANDA are not shielded by the safe harbor, even though they lead to information that must be reported to the FDA.

The *Classen* litigation involved three patents directed towards methods of immunization. The accused infringement consisted in part of the defendants' participation in studies evaluating associations between childhood vaccinations and the risk of developing type 1 diabetes.[32] The accused infringers asserted that their participation in studies evaluating risks associated with different vaccination schedules was reasonably related to their regulatory obligation to review and report adverse events to the FDA.[33] The district court agreed with the defendants and held that they did not infringe due to the statutory safe harbor.

The Federal Circuit reversed this holding on appeal. The majority sided with the patent owner and rejected the contention of the accused infringers that they were protected by the 35 U.S.C. §271(e)(1) safe harbor. According to Judge Newman, in an opinion joined by Chief Judge Rader, the legislative history of the Hatch-Waxman Act indicated that Congress intended the safe harbor only to expedite FDA approval of generic drugs.[34] Further, every prior judicial analysis of the statute had addressed activities performed prior to the award of FDA marketing approval.[35] She therefore asserted that "statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained."[36]

Judge Moore authored a dissenting opinion that would have applied 35 U.S.C. §271(e)(1) to the accused infringement. In her view, the statute included no language restricting its scope to pre-approval activity.[37] Further, in her opinion, the legislative history simply did not speak to whether the statute covered post-approval activity or not.[38] She also observed that the Supreme Court had consistently construed the safe harbor in an expansive manner.[39]

Approximately one year after the release of *Classen*, a different three-judge panel of the Federal Circuit issued the decision of *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals,*

(...continued)

> It shall not be an act of infringement to make, use, offer to sell, or sell within 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.

[30] 659 F.3d 1057 (Fed. Cir. 2011).

[31] Id. at 1071.

[32] Classen, 381 F.Supp.2d at 455.

[33] For example, 21 C.F.R. §600.80 requires "postmarketing reporting of adverse experiences" and 21 C.F.R. §601.70 requires "annual progress reports of postmarketing studies.

[34] 659 F.3d at 1071.

[35] Id.

[36] Id. at 1070.

[37] Id. at 1083.

[38] Id. at 1083-84.

[39] Id. at 1083.

Inc.[40] The *Momenta* panel consisted of Chief Judge Rader, who was part of the majority in *Classen*; Judge Moore, who had dissented in that case; and a third jurist, Judge Dyk. The *Momenta* litigation involved a generic version of LOVENOX® (enoxaparin), a drug that prevents blood clots. Enoxaparin is an artificial version of the naturally occurring molecule heparin.

The Federal Circuit explained that unlike most drugs, heparin does not consist of a single defined molecule, but rather a heterogeneous mixture of molecules that differ in "the length of the polysaccharide chain" and the "component disaccharide units and the corresponding distribution of disaccharide unit sequences in the polysaccharide chains."[41] As a result, in order for a generic product to be considered equivalent to brand-name enoxaparin, the FDA required ANDA applicants to establish five "standards of identity," including equivalence in "disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species."[42] After Amphastar received FDA approval to market generic enoxaparin, Momenta brought suit based upon its patented method of analyzing an enoxaparin sample for the presence or absence of a non-naturally occurring sugar. According to Momenta, Amphastar necessarily infringed its patent because the "FDA requires a generic manufacture[r] to include in its manufacturing process the analysis of each batch of its enoxaparin drug substance to confirm that ... [it] includes a 1,6-anhydro ring structure."[43]

This time writing for the majority, Judge Moore held that Amphastar's activities were shielded from liability for patent infringement by 35 U.S.C. §271(e)(1). She again observed that Supreme Court precedent took an expansive view of the Hatch-Waxman Act's safe harbor provision and that the statute included no language restricting its scope to pre-approval activity.[44] She further distinguished the *Classen* case. According to Judge Moore, the information submitted by Amphastar was not "routinely reported to the FDA" as in *Classen.* Rather, the FDA required Amphastar to test each batch of generic enoxaparin before releasing it to the market.[45] In her view, post-approval activities that are "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" fall within the scope of Hatch-Waxman safe harbor.[46]

Chief Judge Rader contributed a vigorous dissent. In his view, Congress intended 35 U.S.C. §271(e)(1) to permit only "a limited amount of pre-approval experiments to obtain FDA approval."[47] He believed that the holding in *Classen* was controlling and that the *Momenta* majority had strained to "come out the exact opposite way."[48] In his view, Amphastar's testing should not have been shielded by the statutory safe harbor.

The holdings in *Classen* and *Momenta* are arguably quite significant in terms of determining the impact of intellectual property law within the health sciences. The *Classen* majority expressed concerns about the potential breadth of the Hatch-Waxman Act's safe harbor provision. Via

[40] 686 F.3d 1348 (Fed. Cir. 2012).

[41] *Id.* at 1349.

[42] *Id.* at 1350.

[43] *Id.* at 1352.

[44] *Id.* at 1355.

[45] *Id.* at 1357-58.

[46] *Id.* at 1359.

[47] *Id.* at 1367.

[48] *Id.* at 1368.

statute and regulation, the FDA receives a great deal of information from the pharmaceutical industry at all stages of the life cycles of particular products. If 35 U.S.C. §271(e)(1) were to apply to post-approval activities, then a potentially broad swath of activity could be conducted free of the patent system. The *Classen* majority appeared to doubt that Congress intended to limit the value of pharmaceutical patents to this extent.

On the other hand, the *Momenta* majority correctly observes that 35 U.S.C. §271(e)(1) is not restricted to pre-approval activities through its own wording. The extent to which jurists should employ legislative histories and their sense of congressional purposes when construing statutes has been the subject of a longstanding debate that exceeds the scope of this report.[49] In terms of public health policy, the dissenting view would potentially reduce patent barriers to compliance with FDA regulators. This result would arguably come at the expense of intellectual property rights and incentives to bring innovative drugs to market, however.

Were 35 U.S.C. §271(e)(1) to be confined to pre-approval activities, the statutory safe harbor would principally act to regulate the timing of patent litigation. The Hatch-Waxman Act exempts a generic firm from infringement suits as it prepares its ANDA. Once an ANDA is filed, however, 35 U.S.C. §271(e)(2) potentially allows a patent infringement lawsuit to commence. If there were no time limit placed upon resort to the safe harbor, no patent litigation would occur at all with respect to post-approval activities. This distinction possibly motivated the *Classen* majority ruling that limited 35 U.S.C. §271(e)(1) to pre-approval activities despite the statute's literal wording.

The Patent Infringement Provision

Recent judicial developments have also impacted 35 U.S.C. §271(e)(2), the counterpart to the safe harbor provision. This provision has traditionally been understood to allow a patent infringement lawsuit once a generic firm files an ANDA with a paragraph IV certification. For example, the Supreme Court once described 35 U.S.C. §271(e)(2) as establishing "a highly artificial act of infringement that consists of submitting an ANDA ... containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."[50]

The actual text of 35 U.S.C. §271(e)(2) does not seem to require the filing of a paragraph IV ANDA for a brand-name firm to bring a patent infringement lawsuit, however. That statute states in pertinent part:

> It shall be an act of infringement to submit ... an application ... for a drug ... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Whether a cause of action under 35 U.S.C. §271(e)(2) is predicated upon a paragraph IV certification or not holds notable consequences for the Hatch-Waxman system. If such a certification is not required, then the filing of an ANDA could lead to charges of infringement for patents that are not listed in the Orange Book. This state of affairs could potentially limit the

[49] See, e.g., Antonin Scalia, *A Matter of Interpretation: Federal Courts and the Law* (Princeton University Press 1998).

[50] 496 U.S. 661, 678 (1990).

ability of the Orange Book to identify patents that pertain to a particular pharmaceutical and also impact patent enforcement more generally—two factors that may possibly affect the availability of generic medications.

The litigation in *Abraxis Bioscience Inc. v. Navinta LLC*[51] recently highlighted this issue, although the court's disposition of the matter did not conclusively resolve the issue. Abraxis holds the NDA for Naropin® (ropivacaine), a drug used during surgical anesthesia and for acute pain management. Navinta subsequently filed an ANDA with the intention of producing a generic version of this medication. Abraxis had identified only a single patent for listing in the Orange Book, U.S. Patent No. 4,870,086. The '086 patent claims an isomer of ropivacaine hydrochloride monohydrate. Navinta's ANDA included a paragraph IV certification to the '086 patent.[52]

Upon receiving notice of Navinta's paragraph IV ANDA, Abraxis sued Navinta under 35 U.S.C. §271(e)(2). Abraxis brought suit under the '086 patent. But it also alleged infringement of two other patents: U.S. Patent Nos. 5,670,524 and 5,834,489. Each of these patents addresses methods of using ropivacaine for the treatment of pain. But neither was listed in the Orange Book at the time Navinta filed its ANDA.[53] Although Navinta argued that the two method patents should be removed from the litigation, the district court concluded that a lawsuit under 35 U.S.C. §271(e)(2) was appropriate even though neither one was identified in the Orange Book.[54]

Navinta appealed this and other rulings to the Federal Circuit. Navinta cited several cases from the Supreme Court and Federal Circuit that, in its view, held that 35 U.S.C. §271(e)(2) requires a paragraph IV certification on an Orange Book-listed patent. In response, Abraxis pointed to the text of 35 U.S.C. §271(e)(2), which does not state such a requirement. Abraxis also asserted that neither the Supreme Court nor the Federal Circuit has ever directly held that a paragraph IV certification is a prerequisite to suit under 35 U.S.C. §271(e)(2).

On appeal, the Federal Circuit acknowledged this issue but did not address it. The court of appeals instead resolved the dispute between Abraxis and Navinta on a different basis. Abraxis ultimately purchased all three asserted patents from several other firms through a complex series of transactions. However, at the time it filed suit against Navinta, Abraxis was not the actual owner of the patents due to a break in the chain of title. Because Abraxis therefore lacked standing to assert the patents on the date it filed suit, the Federal Circuit ruled that its complaint should be dismissed.[55]

This issue may yet be placed before the courts in the future. Because Abraxis currently owns all three asserted patents, it now possesses the ability to file an infringement suit against Navinta. Other firms may potentially assert patents that are not listed in the Orange Book under 35 U.S.C. §271(e)(2) as well.

The scope of 35 U.S.C. §271(e)(2) potentially holds important consequences for the Hatch-Waxman system. The Orange Book essentially serves as a patent clearinghouse that allows generic firms to identify the intellectual property rights that protect brand-name pharmaceuticals.

[51] 625 F.3d 1359 (Fed. Cir. 2010).

[52] 625 F.3d at 1360-61.

[53] Id. at 1361-62.

[54] Id. at 1362-63.

[55] Id. at 1365.

To assist in this role, the Hatch-Waxman Act requires NDA applicants to identify appropriate patents that the FDA subsequently places in the Orange Book.[56] Although the statute offers certain advantages to identifying relevant patents,[57] it establishes no fine or other penalty if a brand-name firm fails to do so. The ability of brand-name firms to assert unlisted patents under 35 U.S.C. §271(e)(2) may further decrease their incentives to comply with this statutory obligation.

On the other hand, 35 U.S.C. §271(e)(2) was designed to allow brand-name and generic firms to resolve their patent disputes in a prompt manner. Unlike most patent infringement lawsuits, which focus on a commercially available product, Hatch-Waxman litigation commences before the generic drug is publicly available and even before the FDA has approved the generic drug for marketing. This "head start" may allow the lawsuit to be resolved in a timelier manner. Under this system, litigation involving all pertinent patents—including ones not listed in the Orange Book—might best serve the goals of both the intellectual property and public health systems.

In this respect, it should be appreciated that the Hatch-Waxman Act states particular requirements for the sorts of patents that are appropriately listed in the Orange Book. The statute provides that an NDA applicant must identify to the FDA:

> any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[58]

Stated differently, the statute establishes two requirements for an Orange Book listing. First, the patent must claim a drug, or a method of using a drug, for which the applicant submitted the NDA. Second, the patent proprietor could reasonably assert a claim of infringement of that patent against a proposed generic version of the drug.[59]

Due to this two-part standard, merely because a patent cannot be listed in the Orange Book does not mean that the patent could not be successfully enforced against an unauthorized competitor. Patents claiming methods of manufacture, chemical intermediates, and product packaging are among those that may not be listed, even though they may possibly be infringed.[60] In such cases, exclusion from the Orange Book would not prevent the patent proprietor from bringing suit at such time the generic product was marketed.[61] Allowing litigation under 35 U.S.C. §271(e)(2) for unlisted patents would fulfill the policy goal of prompt resolution of pharmaceutical patent disputes—but also potentially place more intellectual property barriers to generic competition.

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[56] 21 U.S.C. §355(b)(1).

[57] In particular, the FDA grant of marketing approval of a generic version of the patented drug may be delayed by 30 months. 21 U.S.C. §355(j)(5)(B)(iii).

[58] 21 U.S.C. §355(b)(1).

[59] John R. Thomas, *Pharmaceutical Patent Law* 404 (2d ed. Bureau of National Affairs 2010).

[60] See Department of Health and Human Services, Food and Drug Admin., Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003).

[61] See aaiPharma, Inc. v. Thompson, 296 F.3d 227, 241 n.7, 63 USPQ2d 1670, 1679 n.7 (4th Cir. 2002) (noting that the owner of an unlisted patent "can still pursue patent infringement suits against generic manufacturers.").

Congressional Issues and Options

Should Congress conclude that the current situation with respect to 35 U.S.C. §271(e) is satisfactory, no action need be taken. If Congress wishes to intervene, however, then some options present themselves. Congress could stipulate whether 35 U.S.C. §271(e)(1) applies to acts that occur following the award of FDA marketing approval or not. Congress could also explicitly state whether 35 U.S.C. §271(e)(2) establishes a cause of action for infringement of patents that have not been listed in the Orange Book and therefore were not the subject of a paragraph IV certification.

Recent interpretational disputes with respect to 35 U.S.C. §271(e) have drawn attention to potential distinctions between traditional Hatch-Waxman Act practice and the arguably broader wording of that statute. The courts commonly resolve these questions using traditional legal methods of statutory interpretation. But their rulings may significantly impact the two policy goals of the Hatch-Waxman Act: the preservation of incentives to develop innovative medications and the promotion of generic competition. Those who view the availability of new cures and the cost of health care as pressing issues of national importance would do well to track future judicial interpretation of these core Hatch-Waxman Act provisions.

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