

Generic Drug Manufacturers May Be Liable For Patent Infringement Under 35 U.S.C. § 271(e)(2)(A) In The Absence Of Paragraph IV Certification

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On May 16, 2012, Judge Leonard P. Stark of the United States District Court for the District of Delaware held that a generic drug manufacturer may be liable under 35 U.S.C. § 271(e)(2)(A) for patent infringement based on its filing of an Abbreviated New Drug Application ("ANDA") – and consequently may have its ANDA approval withdrawn pursuant to § 271(e)(4)(A) – where the patent issued after FDA approval of the ANDA and was not subject to a Paragraph IV certification. See *Research Found. of State Univ. of New York v. Mylan Pharms., Inc.*, Nos. 09-184, 10-892 (D. Del. May 16, 2012) (Slip. Op.) ("Oracea[®] Remedy Opinion"). [Read the Court's decision here](#). This ruling is another case in recent Federal Circuit and district court law clarifying the scope of § 271(e)(2)(A), a key tool for the enforcement of pharmaceutical patents under the Hatch-Waxman Act.

Background

The Hatch-Waxman Act was designed to allow branded drug manufacturers to bring early patent challenges against generic drug manufacturers, and created a "highly artificial act of infringement" based on the submission of an ANDA, codified at 35 U.S.C. § 271(e)(2)(A).¹ Pursuant to § 271(e)(2)(A):

It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [i.e., an ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . 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 . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The Hatch-Waxman Act created a mandatory statutory remedy for acts of infringement under § 271(e)(2)(A), requiring that "the court shall order the effective date of any approval of the [generic] drug . . . to be a date which is not earlier than the expiration of the patent which has been infringed" See 35 U.S.C. § 271(e)(4)(A).² When an ANDA is approved prior to a finding of infringement under § 271(e)(2)(A), the § 271(e)(4)(A) remedy has the effect of requiring the FDA to revoke final approval, and return the ANDA to "tentative approval" status.³

In 2008, Mylan Pharmaceuticals, Inc. ("Mylan") filed an ANDA for a generic version of the branded product Oracea[®] (30 mg immediate release, 10 mg delayed-release doxycycline capsules) marketed

by Galderma Laboratories, L.P. ("Galderma"). Galderma sued Mylan for infringement of several Orange Book listed patents and obtained a preliminary injunction against Mylan based on two of those patents. However, Mylan was not subject to a 30-month automatic stay of ANDA approval⁴ and its generic Oracea[®] product received FDA approval on July 1, 2010. On July 6, 2010, a new patent covering Oracea[®] issued ("the Chang Patent"), and subsequently, Galderma listed it in the Orange Book. Mylan's ANDA was approved prior to the issuance of the Chang Patent, and Mylan did not amend its ANDA with a Paragraph IV certification regarding the Chang Patent. Mylan brought a declaratory judgment action against Galderma regarding the Chang Patent in October 2010. After a bench trial before Judge Stark of the District of Delaware, the court found all asserted claims of the Chang Patent to be infringed and valid. After rendering its opinion on Mylan's liability for infringing the Chang Patent, the court requested that the parties provide additional guidance on the appropriate remedy.⁵

Judge Stark's Decision

After considering briefing and oral argument from the parties, Judge Stark ordered that, pursuant to § 271(e)(4)(A), FDA is directed to withdraw approval of Mylan's ANDA and that the effective date of approval of Mylan's ANDA shall be a date not earlier than December 19, 2027, the expiration date of the Chang Patent.⁶ Specifically, the court rejected Mylan's argument that a Paragraph IV certification is a "necessary predicate" to an infringement claim under §271(e)(2)(A), holding that "a Paragraph IV certification against the Chang Patent was not required for Galderma to bring suit under Section 271(e)(2)." Citing the Federal Circuit's recent decision in *AstraZeneca Pharms. LP v. Apotex Corp.*,⁷ the court held that it had subject matter jurisdiction over Galderma's infringement claim in view of Galderma's allegation that Mylan's ANDA filing infringed the Chang Patent under § 271(e)(2)(A), and noted that a Paragraph IV certification was not required for subject matter jurisdiction.⁸ However, whereas the generic defendants in *AstraZeneca* were found not to infringe under § 271(e)(2)(A) based on their carving-out of patented methods of treatment from their proposed package inserts,⁹ the court found that Mylan's ANDA product was covered by the Chang Patent and accordingly infringed the Chang Patent under § 271(e)(2)(A).¹⁰ In view of Mylan's liability under § 271(e)(2)(A), the court granted Galderma's request for statutory relief pursuant to § 271(e)(4)(A).

Analysis and Implications

As Judge Stark noted in his opinion, while the Federal Circuit's recent *AstraZeneca* decision made it clear that a court may have subject matter jurisdiction over a § 271(e)(2)(A) infringement claim even where no Paragraph IV certification has been filed, *AstraZeneca* did not directly address the question of whether a generic drug manufacturer that does not submit a Paragraph IV certification can be liable for infringement under § 271(e)(2)(A). Judge Stark's holding that a Paragraph IV certification is not a necessary predicate to liability under § 271(e)(2)(A) is consistent with other Delaware decisions recognizing that nothing in the text of § 271(e)(2)(A) requires a Paragraph IV certification.¹¹ It is also consistent with earlier Federal Circuit and district court cases finding the filing of ANDAs on antibiotic drug products to constitute infringement under § 271(e)(2)(A), even though under the contemporaneous law antibiotic drugs were not subject to the Orange Book listing or patent certification provisions of Hatch-Waxman.¹²

Judge Stark's opinion further holds that approval of an ANDA prior to issuance of an Orange Book listed patent does not preclude application of the statutory remedy of a stay of ANDA approval under § 271(e)(4)(A). In this regard, Judge Stark's holding is consistent with Federal Circuit law holding that § 271(e)(4)(A) has the effect of withdrawing final approval for previously approved ANDAs.¹³

This case adds to the growing body of law holding that branded pharmaceutical companies may bring an infringement suit pursuant to § 271(e)(2)(A) against a potential generic competitor in the absence of a Paragraph IV certification. Such cases include situations where: a patent covering the branded and generic drug products issues after ANDA approval but prior to generic launch;¹⁴ the branded manufacturer asserts a patent that covers the generic drug product, but which is not listed in the Orange Book because it does not cover the branded drug product (e.g., a crystal polymorph patent);¹⁵ and the branded manufacturer neglects to submit a patent to FDA for Orange Book listing within 30 days of its issuance, and thus the generic manufacturer is not required to file an amended patent certification.¹⁶ Such cases have upheld the patentee's ability to bring a patent challenge under § 271(e)(2)(A) without having to wait until generic launch is imminent, and make available the powerful statutory remedy of § 271(e)(4)(A) to delay or reset FDA approval of infringing generic drug products.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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¹ See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). By creating an artificial act of patent infringement, § 271(e)(2)(A) provides the basis for a district court to have subject matter jurisdiction under 28 U.S.C. § 1338(a) over patent challenges prior to the marketing of any infringing generic products. See *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003).

² In addition to the mandatory remedy of § 271(e)(4)(A), injunctive relief may be granted against an infringing generic drug manufacturer under § 271(e)(4)(B). Damages may also be provided under § 271(e)(4)(C), but with the exception of attorneys fees under § 285, monetary relief is only available if the generic drug product has been commercially manufactured, used, offered for sale or sold within the United States or imported into the United States.

³ See *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008).

⁴ As each of the patents-in-suit was listed in the Orange Book only after submission of Mylan's ANDA, these patents could not serve as the basis for a 30-month stay. See 21 U.S.C. § 355(j)(5)(B)(iii).

⁵ See *Research Found. of State Univ. of New York v. Mylan Pharms., Inc.*, 809 F. Supp. 2d 296, 336-37 (D. Del. 2011).

⁶ See *Oracea*® Remedy Opinion at 14. The court also ordered that, pursuant to 35 U.S.C. § 283, Mylan and those in concert with Mylan are enjoined from making, using, offering for sale, selling within the United States, or importing into the United States, Mylan's generic drug product.

⁷ 669 F.3d 1370 (Fed. Cir. 2012).

⁸ See *Oracea*® Remedy Opinion at 9 (citing *AstraZeneca*, 669 F.3d at 1377).

⁹ See *id.* (citing *AstraZeneca*, 669 F.3d at 1379-80).

¹⁰ See *id.* Mylan had stipulated to infringement of many of the asserted claims of the Chang Patent, and Galderma proved Mylan's infringement of other contested claims at trial. See *id.* at 9 n. 7.

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- ¹¹ See, e.g., *Cephalon, Inc. v. Sandoz, Inc.*, No. 11-821-SLR, 2012 WL 682045, at *6 & n.10 (D. Del. Mar. 1, 2012) (Robinson, J.) (rejecting generic defendant's motion to dismiss for failure to state a claim of infringement under § 271(e)(2)(A) where no Paragraph IV certification was filed); *Bristol-Myers Squibb Co. v. Mylan Pharms, Inc.*, No. 09-0651, D.I. 31 (D. Del. Jan. 14, 2010) (Farnan, J.) (same).
- ¹² See, e.g., *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1342-44, 1351 (Fed. Cir. 2004); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829-30 (N.D. Ill. 2004).
- ¹³ See *In re Omeprazole*, 536 F.3d at 1367-68; *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1366-67 (Fed. Cir. 2008).
- ¹⁴ See Oracea® Remedy Opinion at 7-10.
- ¹⁵ See *Bristol-Myers Squibb Co. v. Mylan Pharms, Inc.*, No. 09-0651, D.I. 31 (D. Del. Jan. 14, 2010).
- ¹⁶ See *Cephalon*, 2012 WL 682045, at *1 (citing 21 C.F.R. § 314.94(a)(12)(vi)); but see *Eisai Co., Ltd. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *13-14 (D.N.J. Dec. 20, 2007) (finding no § 271(e)(2)(A) infringement where a patentee repeatedly failed to submit the proper patent information to FDA regarding a patent that should have been listed in the Orange Book).