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A New Court Ruling Shows How Not To Litigate A Follow-On P(iv) ANDA

Forest Laboratories listed two patents for Lexapro®; a broad patent expiring in 2012, and a narrow patent expiring in 2023. Ivax filed the first Paragraph (iv) ANDA, challenging both patents. Forest sued to enforce only the first patent - and won. Yesterday, the Court of Appeals for the Federal Circuit concluded that Ivax, having failed to litigate against the second patent at all, cannot launch a generic before the second patent expires. This is not surprising.

The more interesting aspect involves a later Paragraph (iv) ANDA filed by India's Sun Pharmaceutical. Sun alleges that its product does not infringe Forest's second, narrow patent. The FDA nonetheless refused to approve Sun's ANDA until 180 days after Ivax launches its own product - in 2023. To try to open the market to its own (and others') generic products, Sun sued Forest to invalidate Forest's second patent. The Federal Circuit yesterday ruled that Sun's case can proceed.

This ruling might appear to be a victory for Sun. The ruling confirms, however, that Forest's legal team succeeded in delaying the start of Sun's patent challenge for at least two full years. With annual sales of about US$3.7 billion, these two years are extraordinarily valuable for Forest.

Further, the ruling says that Sun can litigate to obtain a court ruling regarding infringement by *Sun's* product - not by Ivax's product. Thus, Sun can spend several million dollars more in legal fees to obtain a ruling that Sun's product does not infringe Forest's second patent. This ruling, however, will not determine whether *Ivax's* product infringes. Without a court ruling on the Ivax product, the FDA cannot approve the Ivax ANDA - and thus cannot approve Sun's later-filed ANDA. Thus, an eventual win by Sun would appear to be an empty victory. Read more about the case in our Litigation Library. And, our congratulations to Gerald J. Flattmann, Esq. for his team's exceptional legal work on behalf of Forest Laboratories.

United States Court of Appeals for the Federal Circuit

2007-1404

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff-Appellant,

v.

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
and H. LUNDBECK A/S,

Defendants-Appellees.

Appeal from the United States District Court for the Eastern District of Michigan in case no. 07-CV-10737, Chief Judge Bernard A. Friedman.

DECIDED: April 1, 2008

Before GAJARSA, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and PROST, Circuit Judge.

Opinion for the court filed by Circuit Judge GAJARSA. Dissenting opinion filed by Circuit Judge FRIEDMAN.

GAJARSA, Circuit Judge.

This is an action brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the provision of the Hatch-Waxman Act establishing civil actions for patent certainty, 21 U.S.C. § 355(j)(5)(C). Plaintiff-Appellant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") appeals a decision of the United States District Court for

the Eastern District of Michigan dismissing its declaratory judgment action for noninfringement against Defendants-Appellees Forest Laboratories, Inc., et al., ("Forest"). Caraco's action was dismissed for lack of Article III jurisdiction on the grounds that it had been rendered moot when Forest unilaterally granted Caraco a covenant not to sue for infringement of the patent-in-suit, U.S. Patent No. 6,916,941. However, in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties. Accordingly, we hold that Caraco's declaratory judgment action presents a continuing Article III controversy, and reverse and remand for further proceedings.

I. BACKGROUND

This case arises under the Hatch-Waxman Act,[1] which governs the Food and Drug Administration's ("FDA") approval of new and generic drugs. The goal of the Act is to "[strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). The following five aspects of the Hatch-Waxman framework are relevant to this case.

First, a pioneering drug company must obtain FDA approval for its drug by submitting a New Drug Application ("NDA"). See 21 U.S.C. § 355(a), (b). As part of the NDA process, the drug company must inform the FDA of all patents covering its drug or

[1] The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

the methods of using the drug, "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." See 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists all such patents in a publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations." This publication is commonly known as the "Orange Book." Drugs approved by the FDA are known as "listed drugs." See 21 U.S.C. § 355(j)(2)(A)(i).

Second, to facilitate the development of generic versions of listed drugs, the Hatch-Waxman Act provides an Abbreviated New Drug Application ("ANDA") process for generic drug manufacturers. See 21 U.S.C. § 355(j). The ANDA process streamlines FDA approval of generic drugs by allowing applicants to rely on the results of the safety and efficacy studies that supported the FDA's approval of a listed drug. See id.; Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). Under the ANDA process, a generic drug company must submit information to show, inter alia, that its generic drug and the relevant listed drug share the same active ingredients and are bioequivalent. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). In addition, generic drug companies must submit one of four certifications addressing each Orange-Book-listed patent covering the listed drug. Specifically, the ANDA filer must certify—

> (I) that [the required] patent information has not been filed [with the FDA],
> (II) that such patent has expired,
> (III) of the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). If a generic drug company seeks to market a generic version of a listed drug before the expiration of Orange-Book-listed patents covering

that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a "Paragraph IV certification." See Eli Lilly, 496 U.S. at 677. All Paragraph IV ANDA filers must provide notice of their Paragraph IV certification to both the patent owner and the NDA holder. 21 U.S.C. § 355(j)(2)(B). This notice must set forth a "detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

Third, the Hatch-Waxman Act facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2); Eli Lilly, 496 U.S. at 678. The Act states that "it shall be an act of infringement" to submit an ANDA "if the purpose of such submission is to obtain approval . . . 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." 35 U.S.C. § 271(e)(2). As this court has explained, "§ 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004) (emphasis in original); see also Eli Lilly, 496 U.S. at 678 ("Quite obviously, the purpose of subsection[] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s].")

Fourth, to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification ("first Paragraph IV ANDA filer") shall enjoy a 180-day period of generic marketing exclusivity. See 21 U.S.C.

§ 355(j)(5)(B)(iv). Until the first Paragraph IV ANDA filer's exclusivity period expires, the FDA may not approve a later-filed Paragraph IV ANDA based on the same NDA (hereinafter a "subsequent Paragraph IV ANDA"). Id. Importantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period whether or not it establishes that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its ANDA; all that is required is that the first Paragraph IV ANDA filer submit a substantially complete ANDA that contains a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

The Hatch-Waxman Act provides that the 180-day period of exclusivity begins either on the date that the first Paragraph IV ANDA filer begins marketing its generic drug, or on the date of a final court decision finding the relevant Orange-Book-listed patents invalid or not infringed, whichever comes first. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000)[2]; see also Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1328 (Fed. Cir. 2005) ("Pfizer"). In other words, the applicable statutory provisions provide for two methods of triggering the first Paragraph IV ANDA filer's 180-day exclusivity period: (1)

[2] In 2003, Congress replaced the provisions governing the commencement of the 180-day exclusivity period with a new regime under which the first Paragraph IV ANDA filer can forfeit its exclusivity period if it fails to market its drug within a certain time. See 21 U.S.C. § 355(j)(5)(D); see also Pfizer, 395 F.3d at 1329. The amendment was part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("Medicare Modernization Act" or "MMA"), which was enacted on December 8, 2003. Pfizer, 395 F.3d at 1328-29. Despite these changes, the MMA contained a grandfather provision specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the MMA. See MMA § 1102(b). The amendments also do not apply if another generic drug company had filed a Paragraph IV ANDA for the same listed drug before the date of enactment of the MMA. Id. In this case, a generic drug company, namely Ivax Pharmaceuticals, Inc., filed a Paragraph IV ANDA in August 2003, before the December 2003 enactment of the MMA. Thus, the MMA amendments to the provisions governing the commencement of 180-day exclusivity period are inapplicable to this case.

a commercial-marketing trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) and (2) a court-judgment trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Only the first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). However, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger. Minn. Mining & Mfg. Co. v. Barr Labs., Inc., 289 F.3d 775, 780 (Fed. Cir. 2002) ("3M") (holding that the first Paragraph IV ANDA filer's 180-day exclusivity period can be triggered by a court judgment obtained by a subsequent Paragraph IV ANDA filer).

Since the FDA cannot approve subsequent Paragraph IV ANDAs until the first Paragraph IV ANDA filer's 180-day exclusivity period expires, the date on which the exclusivity period is triggered is critical to NDA holders and subsequent Paragraph IV ANDA filers. On the one hand, subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event. On the other hand, NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period expires. Moreover, because subsequent Paragraph IV ANDA filers can only activate the first Paragraph IV ANDA filer's 180-day exclusivity period through the court-judgment trigger, subsequent Paragraph IV ANDA filers have a strong incentive to challenge the NDA holder's Orange-Book-listed patents in court. Conversely, NDA holders have a strong incentive to avoid litigation that would trigger the first Paragraph IV ANDA filer's

exclusivity period and allow the FDA to approve subsequent Paragraph IV ANDAs 181 days after the triggering event.

For example, if a first Paragraph IV ANDA filer is found liable in a § 271(e)(2) infringement action or simply fails to market its generic drug, then it has not triggered its own exclusivity period through the court-judgment trigger or the commercial-marketing trigger. In that case, a subsequent Paragraph IV ANDA filer must generate a court-judgment triggering event in order to activate the first Paragraph IV ANDA filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); 3M, 289 F.3d at 780. More precisely, the subsequent Paragraph IV ANDA filer must obtain a judgment that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its subsequent Paragraph IV ANDA. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, if the NDA holder can prevent the subsequent Paragraph IV ANDA filer's court challenge, it can delay FDA approval of the subsequent Paragraph IV ANDA and thus delay the subsequent Paragraph IV ANDA filer's entry into the market. See 21 U.S.C. § 355(a) (providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug") Indeed, an NDA holder could thus delay any subsequent Paragraph IV ANDA filer from entering the market until the NDA holder's Orange-Book-listed patents expire.[3]

The fifth and final aspect of the Hatch-Waxman Act relevant to this case is the "civil action to obtain patent certainty" ("CAPC"). See 21 U.S.C. § 355(j)(5)(C). The

[3] Generic drug companies can obtain immediate FDA approval of their drugs when the relevant Orange-Book-listed patents expire by submitting a Paragraph III ANDA certifying that the patents will expire on that date. See 21 U.S.C. § 355(j)(2)(A)(vii)(III).

CAPC is designed to prevent NDA holders from "gaming" the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers. Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("Novartis"). Under the CAPC provisions, if the NDA holder fails to sue a Paragraph IV ANDA filer within 45 days, the ANDA filer can sue the NDA holder to obtain a declaratory judgment that the relevant Orange-Book-listed patents are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C).

In addition, Congress extended federal jurisdiction over CAPCs "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Accordingly, federal courts have jurisdiction over CAPCs to the extent that they present an Article III case or controversy. Novartis, 482 F.2d at 1342. Congress explained the need for broad federal jurisdiction over CAPCs as follows:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.[4]
>
> In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-

[4] The discussion here refers to the "failure to market" provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(D), under which the first Paragraph IV ANDA filer can forfeit its 180-day exclusivity period by failing to market its generic drug. Section 355(j)(5)(D) replaced the 180-day exclusivity period triggering provisions that are applicable to this case, i.e. 21 U.S.C. § 355(j)(5)(B)(iv) (2000), including the court-judgment trigger. See supra note 2 (discussing MMA § 1102(b), 117 Stat. at 2460). Although the legislative discussion here refers to the amended 180-day provisions, this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed. Thus, Senator Kennedy's remarks concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

> day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

II. FACTS

A. Forest's NDA for Lexapro®

Forest holds an approved NDA for its drug Lexapro®, which is used to treat depression and generalized anxiety disorder. Forest currently faces no generic competition for Lexapro®. Forest Labs., Inc. v. Ivax Pharms., Inc., 438 F. Supp. 2d 479, 494 (D. Del. 2006).

As part of the process for filing its Lexapro® NDA, Forest listed two patents in the FDA's Orange Book, namely: U.S. Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The '712 patent includes claims covering substantially pure forms of escitalopram, the active ingredient of Lexapro®. The '941 patent generally covers crystalline particles of escitalopram oxate of a particular size range, as well as dosage forms containing particles of this size range, and methods of manufacturing particles in this size range. The '712 patent expires in 2012; the '941 patent expires in 2023.

B. The First Paragraph IV Challenge to Forest's Orange-Book-Listed Patents for Lexapro® and the Consequences for Subsequent Paragraph IV ANDA Filers

The first ANDA applicant to file a Paragraph IV certification for Forest's '712 and '941 patents was Ivax Pharmaceuticals, Inc. ("Ivax"). Accordingly, Ivax is entitled to 180

days of generic market exclusivity, which will begin either on the day it begins marketing its generic drug, or on the date a court determines that the '712 and '941 patents are invalid or not infringed—whichever comes first. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

Forest responded to Ivax's Paragraph IV ANDA by suing Ivax for infringement of the '712 patent, the earlier of the two patents to expire. Ivax counterclaimed that the '712 patent was invalid. Despite suing Ivax on the '712 patent, Forest did not sue Ivax for infringement of the '941 patent. By holding the '941 patent in reserve, Forest insulated itself from an invalidity or noninfringement challenge by Ivax.[5] Ultimately, Forest defeated Ivax's counterclaim of invalidity on the '712 patent and obtained a judgment that the drug described in Ivax's ANDA infringed the '712 patent, which was affirmed by this court in Forest Labs., Inc. v. Ivax Pharms., Inc., 501 F.3d 1263 (Fed. Cir. 2007).

In sum, after filing a Paragraph IV certification for both the '712 and '941 patents in its ANDA, Ivax failed to obtain a court judgment that either the '712 or the '941 patent is invalid or not infringed by the drug described in its ANDA. Because Ivax has not obtained a judgment that both of Forest's Orange-Book-listed patents are invalid or not infringed by the generic drug described in its ANDA, Ivax failed to trigger its 180-day exclusivity period via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).

[5] As will be discussed in more detail later, in Novartis this court held that where an NDA holder brings an infringement suit against a Paragraph IV ANDA filer on only one of several Orange-Book-listed patents covering its NDA, the ANDA filer has standing to seek a declaratory judgment on any of the NDA holder's remaining Orange-Book-listed patents for that NDA. 482 F.2d at 1346. However, Novartis had not been decided at the time of Forest and Ivax's dispute, and in any case, Ivax never sought a declaratory judgment that Forest's '941 patent was invalid or not infringed by its generic drug, see Ivax Pharms., Inc., 501 F.3d at 1265.

In addition, because the generic drug described in Ivax's ANDA was found to infringe the '712 patent, Ivax cannot trigger its 180-day exclusivity period via the commercial-marketing trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000), until the '712 patent expires in 2012. Indeed, the district court specifically enjoined Ivax from "making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '712 patent, including the [drug] products referred to in [Ivax's ANDA] until such time as the '712 patent expires . . . ." Forest Labs., Inc. v. Ivax Pharms., Inc., No. 03-891-JJF (D. Del. Nov. 3, 2006) (Judgment Order). As a result, Ivax cannot activate its exclusivity period via the commercial-marketing trigger until the '712 patent expires.

With Ivax no longer able to trigger its exclusivity period, only two pathways remain open to subsequent Paragraph IV ANDA filers who seek to trigger Ivax's exclusivity period before the '712 patent expires in 2012. First, a subsequent Paragraph IV ANDA filer could obtain a court judgment invalidating the '712 patent, which would allow the FDA to approve Ivax's drug. With FDA approval, Ivax would be legally free to sell its generic drug, and its exclusivity period would be triggered on the day of its first commercial marketing. See 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) (the "commercial-marketing trigger"). Second, a subsequent Paragraph IV ANDA filer could trigger Ivax's exclusivity period immediately—regardless of when Ivax begins marketing its drug—via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, because Ivax was the first Paragraph IV ANDA filer with respect to both the '712 and '941 patents, a subsequent Paragraph IV ANDA filer can only activate Ivax's exclusivity

period via the court-judgment trigger by obtaining a judgment that both the '712 and '941 patents are invalid or not infringed.

If a subsequent Paragraph IV ANDA filer is not able to pursue either of these two pathways to triggering Ivax's exclusivity period, then Ivax's exclusivity period cannot begin until the '712 patent expires in 2012. Moreover, assuming there has been no other triggering event by that time, Ivax's exclusivity period will not be triggered on the date the '712 patent expires unless Ivax actually begins marketing its generic drug on that date. Even if Ivax does so, the FDA will still be restricted from approving any subsequent Paragraph IV ANDA until 181 days after the date the '712 patent expires.[6] See 21 U.S.C. § 355(j)(5)(B)(iv).

In short, absent an event triggering Ivax's exclusivity, all subsequent Paragraph IV ANDA filers, including Caraco, will be denied entry to the drug market for a significant time. These subsequent Paragraph IV ANDA filers will be precluded from the market regardless of whether the generic drugs described in their ANDAs infringe Forest's Orange-Book-listed patents and regardless of whether Forest's patents are valid.

C. Caraco's Subsequent Challenge to Forest's Orange-Book-Listed Patents for Lexapro®

In May 2006, Plaintiff-Appellant Caraco filed an ANDA for generic escitalopram that included a Paragraph IV certification for Forest's '712 and '941 patents for Lexapro®. Under 35 U.S.C. § 271(e)(2), this constituted a technical act of infringement of both patents. Forest sued Caraco for infringement of the '712 patent in a lawsuit filed

[6] When the '712 patent expires, subsequent Paragraph IV ANDA filers will not be able to obtain immediate FDA approval by filing a Paragraph III certification; obtaining FDA approval by filing a Paragraph III certification will not be an option until Forest's other Orange-Book-listed patent covering Lexapro®, the '941 patent, expires in 2023. See 21 U.S.C. § 355(j)(2)(A)(vii)(III).

in the Eastern District of Michigan, Forest Labs., Inc., v. Caraco Pharm. Labs., Ltd., Case No. 2:06-EV-13143-BAF-MKM.[7] As of the time of this writing, the parties' litigation with respect to the '712 patent is ongoing.

Despite suing Caraco for infringement of the '712 patent, Forest did not sue Caraco on the '941 patent. However as discussed above, under the Hatch-Waxman framework Caraco has an economic interest in determining whether the '941 patent is invalid or not infringed by the drug described in its ANDA, because only a judgment of invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period. See 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Accordingly, Caraco filed a separate action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the Hatch-Waxman provision establishing the CAPC, 21 U.S.C. § 355(j)(5)(C), seeking a declaratory judgment that the drug described in its ANDA does not infringe Forest's '941 patent. Caraco's declaratory judgment action with respect to the '941 patent is the case presently on appeal.

Shortly after Caraco sued Forest for a declaratory judgment on the '941 patent, Forest filed a motion to dismiss Caraco's action pursuant to Fed. R. Civ. P. 12(b)(1) on the grounds that the action did not present a "case" or "controversy" as required by Article III of the Constitution. In its motion, Forest argued that there was no controversy because Caraco did not have a reasonable apprehension of suit on the '941 patent. At the time Forest filed its motion, this court's most recent precedent governing the

[7] It should be noted that by suing Caraco for infringement of the '712 patent, Forest triggered the automatic 30-month stay of FDA approval provided in 21 U.S.C. § 355(j)(5)(B)(iii). Under § 355(j)(5)(B)(iii), "[i]f the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires." Pfizer, 395 F.3d at 1328.

justiciability of declaratory judgment suits applied the reasonable-apprehension-of-suit test to determine whether a justiciable controversy existed. See, e.g., Pfizer, 395 F.3d at 1332. However, as is discussed in more detail below, even before Forest filed its motion, the Supreme Court found the reasonable-apprehension-of-suit test inconsistent with its precedent. MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 774 n.11 (2007). The Court explained in MedImmune that whether a declaratory judgment action presents an Article III controversy must be determined based on "all the circumstances," not merely on whether the declaratory judgment plaintiff is under a reasonable apprehension of suit. Id. at 771.

In addition, after Forest filed its motion to dismiss but before the district court made its ruling, this court issued its decision in Novartis, 482 F.3d 1330. As in the present case, the issue in Novartis was whether a Paragraph IV ANDA filer's declaratory judgment action against an NDA holder presented a justiciable Article III case or controversy. Id. at 1335. In Novartis, Teva Pharmaceuticals USA, Inc. ("Teva") was the first ANDA applicant to file a Paragraph IV certification on all five Orange-Book-listed patents covering an FDA approved drug owned by Novartis Pharmaceuticals Corp. ("Novartis"). Id. at 1334. Although Teva had filed a Paragraph IV certification for all five of Novartis' Orange-Book-listed patents, Novartis only brought suit under 25 U.S.C. § 271(e)(2)(A) for infringement of one of those patents.[8] Id.

After Novartis filed suit, Teva brought a separate action against Novartis on the four remaining Orange-Book-listed patents. Id. at 1335. However, the district court

[8] Even though Novartis only sued Teva on one of its Orange-Book-listed patents, this was sufficient to trigger a 30-month stay barring Teva's ANDA from approval under 21 U.S.C. § 355(j)(5)(B)(iii). Novartis, 482 F.3d at 1340 n.5.

dismissed Teva's declaratory judgment action for lack of a justiciable controversy on the grounds that Teva had no reasonable apprehension of suit on the four remaining Orange-Book-listed patents. Id. This dismissal was the subject of the appeal in Novartis. Id. On appeal, the court observed that the Supreme Court's MedImmune decision had abrogated the reasonable-apprehension-of-suit test, Novartis, 482 F.3d at 1339, and applying the Supreme Court's all-the-circumstances test, the court found that there was a justiciable controversy between the parties, id. at 1346. In reaching this decision, the court held that—

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

Id. at 1344.

In thus applying the all-the-circumstances test to a declaratory judgment action between an ANDA filer and a pharmaceutical patentee, the Novartis decision eliminates Forest's argument that Caraco's declaratory judgment action should be dismissed because Caraco had no reasonable apprehension of suit on the '941 patent. After the Novartis decision issued, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent. Forest's stated goal in granting the covenant to Caraco was "to confirm" that there was no case or controversy between the parties regarding the '941 patent. Forest's covenant provides, in relevant part:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA

> 78-219 or any commercial manufacture, use, sale, offer for sale or importation of the generic products described by ANDA 78-219.

Notably, despite giving Caraco this covenant not to sue, Forest refused to concede that the '941 patent was invalid or not infringed by the drug described in Caraco's ANDA. In fact, Forest hinged its entire argument for dismissal on the covenant not to sue, stating: "There is no controversy because we gave a covenant not to sue." The district court agreed, stating from the bench that "[t]here's a covenant not to sue on the '941 so there's not going to be any loss, there's no threat of lawsuit." Transcript of Hearing on Motion to Dismiss at 31 (May 30, 2007) (emphasis added). On this basis, the district court ruled that there was no Article III controversy and granted Forest's motion to dismiss. Notably, there is no indication in the record that the district court considered either the Supreme Court's MedImmune decision or this court's Novartis decision when making this ruling.

III. ANALYSIS

A district court's dismissal of a declaratory judgment action for lack of jurisdiction presents a question of law that this court reviews de novo. Novartis, 482 F.3d at 1335.

Our starting point in analyzing Caraco's appeal is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), under which Caraco filed this suit. The relevant text of the Act provides:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). It is well established that the phrase "actual controversy" in § 2201(a) includes any controversy over which there is Article III jurisdiction. Aetna Life

Ins. Co. v. Haworth, 300 U.S. 227, 239-40 (1937) (noting that "the word 'actual' is one of emphasis rather than of definition"). In addition, with respect to declaratory judgment actions brought by Paragraph IV ANDA filers against NDA holders to establish noninfringement or invalidity of Orange-Book-listed patents, Congress has specifically granted federal courts subject matter jurisdiction "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Thus, federal courts have subject matter jurisdiction over such actions to the extent that they present an Article III case or controversy. See Novartis, 482 F.3d at 1337.

In MedImmune, the Supreme Court reaffirmed the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement. 127 S. Ct. at 771. Specifically, the Court framed the justiciability inquiry as "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)). In addition, the Supreme Court emphasized that Article III requires that the dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" Id. (quoting Aetna Life Ins., 300 U.S. at 240-41).

In Novartis this court held that we must "follow MedImmune's teaching to look at 'all the circumstances' to determine whether [an action for a declaratory judgment of noninfringement or patent invalidity presents] a justiciable Article III controversy." 482

F.3d at 1339. Accordingly, Novartis acknowledged that this court's reasonable-apprehension-of-suit test was overruled by MedImmune. Id.; see also SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380 (Fed. Cir. 2007). The reasonable-apprehension-of-suit test required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity." Novartis, 482 F.3d at 1339. Following MedImmune, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.

In applying the all-the-circumstances test to Caraco's declaratory judgment action, we are guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy. In particular, an action is justiciable under Article III only where (1) the plaintiff has standing, Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992), (2) the issues presented are ripe for judicial review, Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967), and (3) the case is not rendered moot at any stage of the litigation, United States Parole Comm'n. v. Geraghty, 445 U.S. 388, 397 (1980). For the following reasons, we hold that Caraco's declaratory judgment action satisfies these requirements and presents a justiciable Article III controversy.

A. Standing

The Supreme Court has explained that the "irreducible constitutional minimum of standing" contains the following three requirements:

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact"—a harm suffered by the plaintiff that is "concrete" and actual or imminent, not "conjectural" or "hypothetical." Second, there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability—a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03 (1998) (internal citations omitted).

1. Caraco Alleges a Judicially Cognizable Injury-in-Fact

In this case, as in most declaratory judgment actions in the patent context, Caraco's alleged injury-in-fact is a "restraint on the free exploitation of non-infringing goods," Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355, 1360 (Fed. Cir. 1998). Here, Caraco alleges it is being excluded from selling a non-infringing product because Forest has taken actions that delay the FDA from approving Caraco's ANDA. See Novartis, 482 F.3d at 1340 (observing that an ANDA filer suffers the requisite injury-in-fact where its ability to secure approval of its ANDA has been prevented by an NDA holder).

As this court explained in Novartis, the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer . . . is not legally free to enter the market [without FDA approval]." 482 F.3d at 1345. Indeed, 21 U.S.C. § 355(a) provides that "[n]o person shall introduce or deliver

for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug." Thus, by preventing the FDA from approving the ANDAs of generic drug manufacturers, pharmaceutical patentees like Forest can potentially exclude non-infringing generic drugs from the market. If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact. Moreover, the fact that Forest's actions can only exclude Caraco from the drug market in the context of the Hatch-Waxman framework does not render Caraco's injury any less "concrete, actual or imminent." Steel Co., 523 U.S. at 102-03.

In sum, Caraco alleges that it has been "restrain[ed from] the free exploitation of non-infringing goods," Red Wing Shoe, 148 F.3d at 1360. This is exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw. See id.; see also Novartis, 482 F.3d at 1345 (explaining that an NDA holder's use of an Orange-Book-listed patent to exclude a generic drug maker from the market creates "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action [i.e. the CAPC, 35 U.S.C. § 355(j)(5)(C)] was enacted to prevent").[9]

[9] Even before the MedImmune and Novartis decisions, the District of Columbia Circuit came to a similar conclusion. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998). In Mova, the court made the following observation:

> [T]he Federal Circuit has had no occasion to decide whether there is "a controversy of sufficient immediacy and reality" to support a declaratory judgment action, when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck,

2. Caraco's Injury Is Traceable to Forest

Caraco's injury is also "fairly traceable [to] the complained-of conduct of the defendant," Steel Co., 523 U.S. at 102-03. It is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather Forest's actions in the context—i.e. "under all the circumstances," MedImmune, 127 S. Ct. at 771—of the Hatch-Waxman framework. Simply put, if Forest had not listed its '712 and '941 patents in the FDA's Orange Book as valid patents covering the drug described in its NDA for Lexapro®, then 21 U.S.C. § 355(j)(5)(B)(iv) (2000) would not independently delay Caraco's ANDA from being approved by the FDA. Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing. See Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 74-78, 81 n.26 (1978).

As discussed above, where the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely. Moreover, this delay occurs even if the drug described in the subsequent Paragraph IV ANDA does not infringe the Orange-Book-listed patents. Here, Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug. Under these circumstances, Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book

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> might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

Id. (internal citation omitted).

creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing. See, e.g., Ne. Fla. Chapter, Associated Gen. Contractors of Am. v. Jacksonville, 508 U.S. 656, 666 (1993) (holding that the "imposition of [a] barrier" to bid for certain government contracts satisfied the injury-in-fact and causation requirements of Article III standing); Clements v. Flashing, 457 U.S. 957, 962 (1982) (holding that the imposition of an "obstacle to [plaintiff's] candidacy for higher judicial office" satisfied the injury-in-fact and causation requirements of Article III standing); Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 124-25 (1969) (holding that the plaintiff had standing to sue where it alleged that it had been denied a share of the market).

3. Caraco's Injury Is Redressible by a Favorable Judgment

Finally, Caraco's injury-in-fact is redressible by a declaratory judgment that the '941 patent is not infringed.[10] A favorable judgment in this case would clear the path to FDA approval that Forest's actions would otherwise deny Caraco—namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) to activate Ivax's exclusivity period. If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible. Thus, a favorable

[10] Caraco's injury-in-fact would also be redressed by a judgment that the '941 patent is invalid, but Caraco has not sought a judgment of invalidity in this case.

judgment in this action would eliminate the potential for the '941 patent to exclude Caraco from the drug market.[11]

* * *

In sum, Caraco's declaratory judgment action satisfies the injury-in-fact, causation, and redressibility requirements of standing. Moreover, even beyond satisfying the requirements of Article III standing, Caraco's action is consistent with the basic purpose of the Declaratory Judgment Act. As this court has previously explained, "the purpose of the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987); see also Novartis, 482 F.3d at 1336 n.2 ("The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) 'serve[] the policies underlying the patent laws by enabling a test of the validity and infringement of patents that are . . . being used only as . . . scarecrows.'" (quoting Arrowhead Indus. Water, Inc. v. Ecolochem, 846 F.2d 731, 735 (Fed. Cir. 1988))).

In claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy. See Goodyear Tire & Rubber Co., 824 F.2d at 956; Red Wing Shoe, 148 F.3d at 1360; see generally E. Borchard, Declaratory Judgments 803-04 (2d ed. 1941) (discussing the history of the Declaratory Judgment Act). In particular,

[11] Although we do not so decide, it appears that if Forest would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would redress Caraco's alleged injury-in-fact just as well as any other court judgment. Thus, if Forest's objective in granting the covenant not to sue on the '941 patent was to avoid costly litigation with Caraco, this might be the best approach to resolve the controversy between the parties.

Caraco alleges that Forest's actions exclude it from the market without ever subjecting Forest's '941 patent to a court determination of its scope.[12] Caraco essentially argues that Forest's actions may allow it to "use a restricted [i.e. narrowly drafted] patent to justify much wider claims of infringement," E. Borchard, supra, at 803-04. Indeed, Caraco claims that it is being excluded from the drug market by Forest's '941 patent even though the generic drug described in its ANDA may not infringe the '941 patent.

Finally, Caraco's declaratory judgment action is also consistent with the basic goal of the Hatch-Waxman Act, which is to balance the need for pharmaceutical innovation with the need for generic drug competition. Andrx Pharms., Inc., 276 F.3d at 1371. As previously noted, a significant part of this carefully crafted dialectic balance is encouraging the early resolution of patent disputes when subsequent Paragraph IV ANDA filers are "blocked by a first generic applicant's 180-day exclusivity." See 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).[13]

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[12] As noted earlier, in the present action Caraco does not seek a judgment that the '941 patent is invalid.

[13] Both the dissent and Forest contend that the legislative history of the Hatch-Waxman Act supports the argument that the covenant not to sue moots any and all controversy with Caraco. The legislative history to which the dissent and Forest cite are the following remarks by Senator Edward Kennedy:

> We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a Paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

B. Ripeness

Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Labs., 387 U.S. at 149. As to the first prong, an action is fit for judicial review where further factual development would not "significantly advance [a court's] ability to deal with the legal issues presented." Nat'l Park Hospitality Ass'n v. Dep't of Interior, 538 U.S. 803, 812 (2003). As to the second prong, withholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an "immediate and substantial impact" on the plaintiff. Gardner v. Toilet Goods Ass'n, 387 U.S. 167, 171 (1967).

In this case, both prongs of the ripeness inquiry are satisfied. First, additional factual development would not advance the district court's ability to decide Caraco's action for a declaratory judgment of noninfringement. Caraco has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts

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149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

Despite the arguments of the dissent and Forest, Senator Kennedy's remarks regarding the effect of a covenant not to sue were made when this court applied a "reasonable-apprehension-of-suit" test as the sole test for whether an action seeking a declaratory judgment of invalidity or noninfringement presented a justiciable Article III controversy. See, e.g., Pfizer, 395 F.3d at 1332. Under the reasonable-apprehension-of-suit test, a covenant not to sue would eliminate the controversy between the parties because the generic drug applicant would no longer have a reasonable apprehension of suit by the patentee. However, as discussed earlier, this singular approach to the justiciability of declaratory judgment actions was struck down by the Supreme Court in MedImmune, 127 S. Ct. at 774 n.11. Given this background, Senator Kennedy's comments only emphasize Congress's intent that the jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution. 35 U.S.C. § 271(e)(5). Moreover, it is ultimately the province and duty of the judicial department, not Congress, to discern the limits of Article III jurisdiction. See Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803).

are required to determine whether this drug product infringes the claims of Forest's '941 patent. Second, if Caraco's drug does not infringe Forest's '941 patent, then withholding court consideration of Caraco's declaratory judgment action has the "immediate and substantial impact" of forestalling Caraco's ability to activate Ivax's exclusivity period through the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).[14] As noted earlier, only a judgment of invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Thus, if Caraco's drug does not infringe Forest's

[14] The dissent concludes that delaying resolution of this suit will have no immediate and substantial impact on Caraco. Indeed, the dissent states that the majority opinion "is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved." With all due respect, we disagree. The dissent offers three main reasons to support its conclusion, and we will address each in turn.

First, the dissent states that there is "no basis to conclude that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires." We agree. What the dissent fails to recognize, however, is that the injury upon which Caraco's suit is premised is the delay (in triggering Ivax's exclusivity period) between now and when the '712 patent expires in 2012, not any delay (in triggering Ivax's exclusivity period) after the '712 patent expires. Thus, the dissent is in error when it notes that our analysis requires speculating as to when Ivax decides to market its drug after the '712 patent expires.

Second, the dissent states that we assume that a first Paragraph IV ANDA filer who unreasonably delays in marketing its drug cannot lose its right to exclusivity. The dissent is incorrect. Our conclusion that the first filer in this case, i.e. Ivax, cannot forfeit its exclusivity period is not based on an assumption, but rather the texts of the Hatch-Waxman Act and the MMA. See discussion supra note 2. As discussed, the MMA amendments to the Hatch-Waxman Act include a grandfather provision that specifically exempts a certain class of Paragraph IV ANDA filers, including Ivax, from being subject to the MMA's 180-day exclusivity forfeiture provisions. Accordingly, it cannot plausibly be argued that Ivax may nevertheless forfeit its exclusivity period.

Third, the dissent states that our analysis "assumes that [Caraco] will prevail in its non-infringement claim—an uncertain assumption at best." We make no such assumption, nor need we. A plaintiff need not prove it will prevail on the merits of its case in order to prove that it has standing to bring the case. Steel Co., 523 U.S. at 89 ("It is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case.").

’941 patent, then delaying court consideration of Caraco’s declaratory judgment action on the ’941 patent delays the date on which the FDA is authorized to approve Caraco’s ANDA. Specifically, Caraco would be delayed until at least 181 days after the ’712 patent expires in 2012. Because Caraco cannot market its generic drug without FDA approval, being delayed from resolving its claim to noninfringement of the ’941 patent creates a potential for lost profits. Accordingly, Caraco’s action is ripe for judicial review.

C. Mootness

The mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action. Geraghty, 445 U.S. at 397. The Supreme Court has articulated the mootness standard as follows:

> Simply stated, a case is moot when the issues presented are no longer “live” or the parties lack a legally cognizable interest in the outcome. Where one of the several issues presented becomes moot, the remaining live issues supply the constitutional requirement of a case or controversy.

Powell v. McCormack, 395 U.S. 486, 496-97 (1969) (internal citations omitted). The question here is whether Forest’s unilateral covenant not to sue Caraco on the ’941 patent renders Caraco’s declaratory judgment action moot.

To be sure, Forest’s covenant not to sue eliminates any reasonable apprehension of suit on the ’941 patent. If a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco’s case and divest the district court of Article III jurisdiction. See, e.g., Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058-59 (Fed. Cir. 1991). But see Fort James Corp. v. Solo Cup Co., 412 F.3d 1340, 1347-49

(Fed. Cir. 2005) (holding that a patentee's covenant not to sue an alleged infringer after a jury verdict of noninfringement did not moot the alleged infringer's counterclaim for unenforceability). However, Caraco does not only allege that it has a reasonable apprehension of suit on the '941 patent. Caraco also alleges that the listing of the '941 patent in the Orange Book effectively prevents Caraco from entering the drug market. Essentially, Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context.

Clearly, in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace. Indeed, a covenant not to sue on a patent ensures that the covenant's recipient will not be liable for damages or subject to an injunction for infringement of that patent. However, in the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval. Moreover, an NDA holder's covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA. As discussed above, where the first Paragraph IV ANDA filer fails to trigger its own exclusivity period, a subsequent Paragraph IV ANDA filer can only obtain FDA approval before the relevant Orange-Book-listed patents expire by obtaining a judgment that those patents are invalid or not infringed. Such a judgment is required to trigger the first Paragraph IV ANDA filer's exclusivity period and thus allow the FDA to approve the subsequent Paragraph IV ANDA 181 days after the triggering event. Under these circumstances, even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes "a

substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, 127 S. Ct. at 771.

Here, Forest's covenant not to sue Caraco does not allow Caraco to enter the generic drug market. Only by obtaining a judgment of noninfringement on both the '712 and '941 patents can Caraco trigger Ivax's 180-day exclusivity period, which currently prevents the FDA from approving Caraco's ANDA. Without a judgment of noninfringement on the '941 patent, even if Caraco prevailed against Forest in the separate infringement action on the '712 patent, Caraco would not be able to activate Ivax's exclusivity period via the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Moreover, until Ivax's exclusivity period expires, the FDA cannot approve Caraco's ANDA. See 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Thus, terminating this action without a judgment with respect to infringement on the '941 patent could delay FDA approval of Caraco's ANDA and thereby exclude Caraco from the drug market, even if its generic drug does not infringe the '941 patent. In these circumstances, Forest's covenant not to sue Caraco does not eliminate the controversy between the parties.

In sum, Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's Orange-Book-listed '941 patent. This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market. Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether

Forest's '941 patent is infringed by the drug described in Caraco's ANDA. Accordingly, we hold that this action presents an ongoing Article III case and controversy.

IV. CONCLUSION

For the foregoing reasons, we reverse the district court's decision dismissing Caraco's declaratory judgment action and remand for further consideration.

REVERSED AND REMANDED

United States Court of Appeals for the Federal Circuit

2007-1404

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff-Appellant,

v.

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
and H. LUNDBECK A/S,
Defendants-Appellees.

Appeal from the United States District Court for the Eastern District of Michigan in case no. 07-CV-10737, Chief Judge Bernard A. Friedman.

FRIEDMAN, Senior Circuit Judge, dissenting.

I would affirm.

I

A. In most instances an alleged infringer seeks a declaratory judgment of non-infringement or patent invalidity to protect itself from a subsequent judicial determination that has a significant adverse financial impact upon the infringer. The present case involves no such danger or possibility, since the covenant not to sue precludes Forest (the proprietary manufacturer) from subjecting Caraco (the generic manufacturer) to damages for infringement of the '941 patent.

Here Caraco's reason for seeking a declaratory judgment of non-infringement is quite different. Its concern is not that it may be sued for infringement if it markets its generic version of the patented drug, but that unless it can obtain a present judicial

determination of that issue, its ability to enter the market may be delayed. This claim stems from and is based upon the particular provisions of the Hatch-Waxman Act.

Under that Act someone seeking to market a generic version of a patented drug files an Abbreviated New Drug Application (known as an "ANDA"). The filing of an ANDA constitutes an act of infringement. If, within forty-five days of receiving a notice of such filing that alleges that the patent on the drug is invalid or that the proposed generic drug does not infringe the patent, the proprietary manufacturer sues the generic manufacturer for infringement, the Food and Drug Administration cannot approve the ANDA for thirty months. The Act also provides that the first generic manufacturer to file an ANDA covering the patented drug has the exclusive right to sell such generic product for 180 days following the first sale of the generic product or a court decision holding the patent invalid or not infringed. This provision, under which the 180-day period of exclusivity is triggered by a judicial decision holding the patent invalid or not infringed, is the basis for Caraco's contention that there was an actual case or controversy before the district court despite Forest's covenant not to sue for infringement.

The theory, as I understand it and as the court apparently views it, is that the other generic manufacturers who filed first might not begin to sell their generic product upon either the expiration of the thirty month stay period or of the patents, and because the generic manufacturers cannot begin selling their products until 180 days after the first-filing generic manufacturer begins its sales, the result of such earlier filing by the generic manufacturer may be to delay Caraco's ability to begin marketing its product for a substantial period, or even indefinitely. Caraco thus contends, and the court holds, that it should be able to invoke the alternative statutory triggering mechanism for the

180-day exclusivity period—a judicial determination of patent non-infringement or invalidity—by maintaining its declaratory-judgment litigation.

This argument is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved.

I have no basis for concluding that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires. Indeed, such delay would seem inconsistent with that manufacturer's being the first to file its ANDA—a situation it presumably sought to give it the competitive advantage of having the exclusive right to sell its generic products for the first 180-days after that product went on the market.

The argument also assumes that the 180-day exclusivity period would not begin to run until the generic manufacturer actually begins marketing its product, and any delay in such marketing will simply defer the beginning of the 180-day period. It could plausibly be argued, however, that despite the seemingly absolute nature of the statutory 180-day exclusivity, a generic manufacturer that unreasonably delays the commencement of marketing after the thirty month period and the patent term have expired, loses its right to exclusivity. Indeed, although the issue has not been raised in this appeal, it could be argued that the thirty month period itself terminates if, after triggering that period by suing the generic manufacturer for infringement after it files its ANDA, the proprietary manufacturer in effect vitiates such action by executing a covenant not to sue for infringement and dismissing its infringement suit.

Finally, Caraco's argument assumes that it will prevail in its non-infringement claim—an uncertain assumption at best.

In MedImmune, Inc. v. Genentech, Inc., 549 U.S. ____, 127 S. Ct. 764, 771 (2007), the Supreme Court recently stated that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Considering all the circumstances here, I answer that question negatively.

B. The court twice cites the legislative history of the Hatch-Waxman Act. The "history" that it cites, however, consists exclusively of statements during the debate on the legislation made by Senator Kennedy, whom it describes as the "ranking member" of the Senate committee.

Senator Kennedy, however, was not a sponsor of the legislation. There is no indication that his statements reflected the views of the majority of the committee or of the Senate, or the sponsors of the legislation. In my view, Senator Kennedy's statements do not provide an appropriate or adequate basis for determining the scope and meaning of this legislation. See Garcia v. United States, 469 U.S. 70, 76 (1984) ("In surveying legislative history we have repeatedly stated that the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which 'represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.' We have eschewed reliance on the passing comments of one Member, and casual statements from the floor debates." (citations omitted)).

If, however, Senator Kennedy's comments are an appropriate source for determining the meaning of the statute, I would give considerable weight to his

statement quoted in footnote 14 of the court's opinion, that: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe." I do not agree with the court that this statement "only emphasize[s] Congress's intent that that jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution."

C. The court contends that its decision is appropriate and necessary to avoid a defeat of the objectives Congress sought to achieve in the Hatch-Waxman Act that, it concludes, would result from permitting a proprietary manufacturer to use covenants not to sue to preclude generic manufacturers from obtaining declaratory judgments on patent infringement and validity. To the extent that Congress may conclude that particular judicial interpretations of the Act thwart the purposes of the legislation, it is for Congress, not for this court, to make whatever changes in the Act it deems appropriate.

II

Although I disagree with the court's substantive rulings, I agree with the court's apparent rejection of Forest's contention that Caraco's appeal was frivolous and seeking sanctions of therefor. The appeal presents important questions under the Hatch-Waxman Act that this court has not previously decided. Under no circumstances could the appeal fairly be characterized as frivolous. Indeed, it is difficult to see how an appeal in which the appellant prevails and the appellate court adopts its contentions could be so described.

Perhaps Forest made the frivolity contention under the misguided belief that by doing so it was enhancing its prospects of success on the merits. If that was its view, it was sadly mistaken. In making the frivolity argument, which occupied five pages of its brief, Forest's counsel was neither helping his client's case nor aiding the court in performing its appellate function. In my view, a lawyer who makes such a contention of frivolity—and at the close of his oral argument, Forest's counsel stated he continued to characterize this appeal as frivolous—engages in sanctionable conduct.