United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER INC.,

Defendant-Appellee.

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Appealed from: United States District Court for the District of Massachusetts

Judge Richard G. Stearns

United States Court of Appeals for the Federal Circuit

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TEVA PHARMACEUTICALS USA, INC.,

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v.

PFIZER, INC.,

Defendant-Appellee.

DECIDED: January 21, 2005

Before MAYER*, CLEVENGER, and SCHALL, Circuit Judges.

Opinion for the court filed by Circuit Judge SCHALL. Dissenting opinion filed by Circuit Judge MAYER.

SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. In its ANDA, Teva sought the approval of the Food and

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* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Drug Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft® by Pfizer, Inc. ("Pfizer"). Pfizer holds two patents relating to Zoloft®: U.S. Patent No. 4,356,518 (the "'518 patent") and U.S. Patent No. 5,248,699 (the "'699 patent").

When Teva filed its ANDA, it also filed what is called in Hatch-Waxman parlance a "paragraph III certification." In that certification, Teva stated that it would not market its generic drug until the '518 patent expires. Simultaneously, Teva filed a Hatch-Waxman "paragraph IV certification." In that certification, Teva stated that its generic drug did not infringe the '699 patent or, alternatively, that the '699 patent is invalid. The '699 patent expires after the '518 patent. Pursuant to the provisions of the Hatch-Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva's paragraph IV certification to sue Teva for infringement of the '699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer's receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer's '699 patent or that the claims of the '699 patent were invalid. On December 8, 2003, the district court dismissed Teva's suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C.

§ 2201(a).[1] Teva Pharms. USA, Inc. v. Pfizer Inc., No. 03-CV-10167-RGS (D. Mass. Dec. 8, 2003).

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici,[2] we see no error in the district court's ruling that Teva failed to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

BACKGROUND

I.

A. The Hatch-Waxman Amendments

The Hatch-Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282). In the Amendments, Congress struck 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).

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[1] Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

[2] Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

In order to speed up the approval process for generic drugs, the Amendments provide that a generic drug manufacturer may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. See 21 U.S.C. § 355(j)(2)(A). Under 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to engage in otherwise infringing acts necessary to prepare an ANDA. However, section 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. 35 U.S.C. § 271(e)(2).

The Hatch-Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application . . . and with respect to which a claim of patent infringement could reasonably be asserted . . . ." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(i). If 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. 21 U.S.C. § 355(j)(5)(B)(iii). During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. Id. If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. Id.

The first ANDA applicant to file a paragraph IV certification enjoys a 180-day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to "design around" patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 57 (July 2002). The 180-day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). The original Hatch-Waxman Amendments provided that the commencement of the 180-day exclusivity period could

also be triggered by "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed."[3] Id.

B. The 2003 Medicare Amendments

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). Pursuant to that provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. Id. In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. Id. The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

[3] As discussed in Part I.B., infra, in 2003 Congress enacted a more complex set of provisions relating to the 180-day exclusivity period. However, these new provisions do not apply in this case.

Congress also addressed the statutory scheme surrounding the 180-day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180-day provisions. See 21 U.S.C. § 355(j)(5)(D) (Supp. 2004). However, the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

II.

A. The '518 and '699 Patents

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression and anxiety disorders.[4] Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is directed to a novel crystalline form of sertraline hydrochloride and to a method for preparing it.[5] The commercial embodiment of the '518 and '699

[4] The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent.

[5] The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located

patents is the drug Zoloft®, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual Report, Zoloft® generated revenues for the company in excess of $2 billion in 2002.

B. Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer of generic pharmaceuticals. In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the '518 and '699 patents in the Orange Book in connection with its NDA for Zoloft® tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. Pfizer, Inc. v. Ivax Pharms. Inc., Nos. 00-408, 01-6007 (D.N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a

(Cont'd. . . .)
on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

position to begin marketing its generic version of Zoloft® immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv), to a 180-day generic market exclusivity period. This 180-day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court . . . holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II).

C. Teva's ANDA filing relating to generic sertraline hydrochloride tablets

As noted, in July of 2002, Teva submitted an ANDA to the FDA for its generic version of Zoloft®. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

D. Teva's declaratory judgment action

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its generic version of Zoloft® does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. See Amana Refrigeration, Inc v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999). The district court determined that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2) Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva. With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested interest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared

its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

ANALYSIS

I.

Our starting point is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), the statute under which Teva filed its suit. The Act provides in relevant part as follows:

> 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.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." EMC Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996). Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "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)). Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. Id.; see also Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995) (reaffirming that since its inception, "the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants"). As we summarized in Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 634 (Fed. Cir. 1991): "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."[6]

As noted, this court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. EMC Corp., 89 F.3d at 811. The inquiry focuses on the conduct of both the patentee and the potential infringer. Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. Id.; Amana Refrigeration, 172 F.3d at 855; BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993).

[6] Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's declaratory judgment action. It is to the former question that we turn first.

II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. Gen-Probe, 359 F.3d at 1379. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed the '699 patent in the Orange Book, thereby representing that the patent "could reasonably be asserted" against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45-days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "could be reasonably asserted . . . ." 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. See Capo, Inc. v. Dioptics Med. Prods., 387 F.3d 1352, 1355 (Fed. Cir. 2004) ("More is needed than knowledge or notice of an adversely held patent. . . . The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff."

(citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated that, "[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed. Cir. 1987)). Although relevant to the analysis, neither of the factors upon which Teva relies is dispositive in this case. See BP Chems., 4 F.3d at 980 ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal citation omitted)); Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985) ("The prior patent litigation initiated by Semi-Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable . . . .").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of imminent suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory

judgment." Maryland Casualty, 312 U.S. at 273. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 101 (1998). Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180-day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006. Because Teva is unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding . . . that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced . . . ."

Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory judgment provisions apply to this case.

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) so that it reads as follows:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, "consistent with the Constitution," bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day period.[7]

[7] Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension test serves "primarily prudential not constitutional concerns." (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions such as this to the limits of Article III. Joined by Amicus Curiae the Federal Trade Commission ("FTC"), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180-day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft®. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft® market during the 180-day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In EMC, we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, "to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity." 89 F.3d at 811. Teva, nevertheless, points to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. See Arrowhead, 846 F.2d at 736 (stating that the two-part test is a "test

often useful in evaluating complaints for declaratory judgments in patent cases"); Fina Oil Chem. Co. v. Ewen, 123 F.3d 1466, 1470 (Fed. Cir. 1997) ("Satisfaction of th[e] traditional two-part test is not . . . a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement."); Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1327 (Fed. Cir. 1998) (stating that the two-part test "contributes to policing the boundary between a constitutional controversy . . . and 'a difference or dispute of a hypothetical or abstract character.'" (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement. First, there is nothing in Arrowhead that supports that proposition. In Arrowhead, the court made clear that although the "actual controversy" test in suits requesting a declaration of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." Arrowhead, 846 F.2d at 737. At the same time, the statement from Fina Oil upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d at 1470. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional

requirement of an actual case or controversy has been met.[8] The statement in no way suggests that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from Hunter Douglas, 153 F.3d at 1327, is really just another way of saying what we said in EMC in expounding on the traditional two-part test: "This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy." 89 F.3d at 811. We would only add that we think this case presents just the sort of situation to which the EMC court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman setting. The plain language of the amended statute—that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution"—compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S. 1) in the 108th Congress, it was provided that the filing of a paragraph IV

[8] In Fina Oil, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with 35 U.S.C. § 116 (1994). The statement relied upon by Teva merely reflects that the precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

certification, and the failure of the patentee or NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

> shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in Minnesota Mining and Manufacturing Co. v. Barr Laboratories, 289 F.3d 775, 784 (Fed. Cir. 2002). Judge Gajarsa suggested that "the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement." Id. at 791. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R. 1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R.1 states as follows:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.
>
> Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the

> requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., Fina Oil and Chemical Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.
>
> In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002).[9] In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391 at 836 (2003).

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's application of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular

[9] In Vanguard Research, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. 304 F.3d at 1254. The court held that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

policies served by the Hatch-Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger the commencement of Ivax's 180-day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180-day exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft® with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft® market, not only from Ivax, but from other generic manufacturers as well. These circumstances, Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180-day exclusivity period following expiration of the '518 patent.

With these same considerations in mind, the FTC states that "while in a 'classic patent declaratory judgment suit,' the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting Fina Oil, 123 F.3d at 1476)), a case such as the present one presents a different situation: "[I]n the Hatch-Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17-18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. See Reid v.

Dep't of Commerce, 793 F.2d 277, 284 (Fed. Cir. 1986) ("'The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'" (quoting Griffith v. Oceanic Contractors, Inc., 458 U.S. 564, 576 (1982))). Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases. That is what we would have to do, in order to rule in favor of Teva in this case. That is because in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-à-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

AFFIRMED

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

PFIZER INC.,

Defendant-Appellee.

MAYER, Circuit Judge*, dissenting.

Because the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will face a patent infringement suit, I respectfully dissent.

I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the

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* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. § 156, 271, 282), part one is satisfied in every instance where an ANDA is filed in accordance with 21 U.S.C. § 355(j), because 35 U.S.C. § 271(e)(2) provides that such a filing constitutes an act of infringement sufficient to trigger a justiciable case or controversy. See Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 676-78 (1990) (determining that the purpose for creating an act of infringement in 35 U.S.C. § 271(e)(2) was to "eliminat[e] the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly"); Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

We have never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy. Conversely, we have consistently held that "there is no specific, all-purpose test" for determining the existence of a case or controversy, either. Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735-36 (Fed. Cir. 1988) (describing the traditional two-part test as "often useful in evaluating complaints for declaratory judgments" but not mandatory in every instance). We have clarified that the "[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the

subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement."

Fina Oil, 123 F.3d at 1470.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction."). "As in all cases our task is to interpret the words of [the statute] in light of the purposes Congress sought to serve." Chapman v. Houston Welfare Rights Org., 441 U.S. 600, 608 (1979).

II.

Because Teva filed an ANDA pursuant to 21 U.S.C. § 355(j) against Pfizer's '699 patent listed in the Orange Book, our application of the traditional test for an "actual controversy" turns solely on whether Pfizer has taken actions that give rise to a reasonable apprehension that it will sue Teva for infringement. The trial court dismissed Teva's declaratory judgment claim saying that no "actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. Teva Pharms. USA, Inc. v. Pfizer, Inc., No. 03-CV-10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

The 2003 amendments to the Hatch-Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(i)). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) (2003).

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201 (2000). This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1053 (Fed Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement of 'injury in fact.'" Schlesinger v. Reservists Comm. to Stop the War, 418 U.S. 208, 218 (1974) (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In Nashville, Chattanooga & St. Louis Railway Co. v. Wallace, 288 U.S. 249, 259 (1933), the Court determined that it should "look not to the label which the Legislature has attached to the procedure followed in the state courts, or to the description of the judgment which is

brought here for review, in popular parlance, as 'declaratory,' but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in Aetna Life Insurance Co. v. Haworth decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory judgments in appropriate cases. 300 U.S. 227 (1937). The Court "observed that the controversy would admit '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.'" Calderon v. Ashmus, 523 U.S. 740, 746 (1988) (quoting Aetna, 300 U.S. at 241). Important to this case, the Court has "thus recognized the potential for declaratory judgment suits to fall outside the constitutional definition of a 'case' in Article III: a claim 'brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs.'" Id. (quoting Fairchild v. Hughes, 258 U.S. 126, 129 (1922)). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch-Waxman and corresponding Medicare Amendments – the key issue being whether the courts are capable of achieving a final or conclusive determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004). The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Id. "Although

the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002) (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch-Waxman requires a thorough analysis of the consequences and repercussions of each party's actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "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 any generic sertraline hydrochloride drug covered by the claims of the '699 patent. 21 U.S.C. § 355(b)(1) (2003). Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[] quiescent patent owners against unwarranted litigation." Arrowhead, 846 F.2d at 736. Pfizer is not a defendant that "has done nothing but obtain a patent." Id. By listing its patent in accordance with 21 U.S.C. §§ 355(b)(1) & (c)(2), Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch-Waxman

establishes that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court . . . holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." Id. § 355(j)(5)(B)(iv)(I-II). A court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise. See 3M v. Barr Labs., Inc., 289 F.3d 775, 778 (Fed. Cir. 2002). If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although Congress' intention was for Hatch-Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies to "park" the 180-day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45-day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i)

180 days after the first ANDA applicant enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180-day period. Essentially, the framework of Hatch-Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the relevant patent.

Taking into account the specific regulatory context of the Hatch-Waxman regime, the "reasonable apprehension" test applied "to the extent consistent with the Constitution" is satisfied by Pfizer's conduct. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction" and the courts should "examine as part of their analysis the particular policies served by the Hatch-Waxman Act."). Cases arising under Hatch-Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. See Fina Oil, 123 F.3d at 1470 (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch-Waxman regime, a subsequent ANDA applicant is not free to market—the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer has already taken

concerning its patents and the likelihood of a future patent suit after the running of the 180-day period.

Against the backdrop of Hatch-Waxman, the totality of Pfizer's conduct must also be considered. See H.R. Conf. Rep. No. 108-391, at 836 (2003) ("In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days]."). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer's belief that its '699 patent is valid and its intent to assert the patent against infringers. "Related litigation may be evidence of a reasonable apprehension." Shell Oil Co. v. Amoco Oil Co., 970 F.2d 885, 888 (Fed. Cir. 1992). Pfizer also has a history of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft®, produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman

regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.