No. 04-1186

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant,

v.

PFIZER, INC., Defendant-Appellee.

On Appeal from the United States Court for the District of Massachusetts
In Case No. 03-CV-10167, The Honorable Richard G. Stearns.

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION SUPPORTING APPELLANT AND URGING REVERSAL

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STATEMENT OF INTEREST

The Federal Trade Commission is an independent administrative agency charged with promoting the efficient functioning of the marketplace and protecting consumer interests. Congress intended the Hatch-Waxman Act[1] to increase the flow of pharmaceuticals into the marketplace by balancing incentives for innovation by research-based pharmaceutical companies with opportunities for market entry by generic drug manufacturers. *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48. Consumers have benefitted from sales of lower-cost generic versions of prescription drugs. Indeed, consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone.[2] For any given drug, entry by more than one generic competitor typically increases the price savings.[3] The Commission therefore has an interest in ensuring that the Hatch-Waxman balance is maintained.

The Commission has developed significant expertise regarding the pharmaceutical industry and the operation of Hatch-Waxman. In 2002, the Commission completed a study of 104 drug products for which at least one

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[1] The Drug Price Competition and Patent Term Restoration Act of 1984, P.L. No. 98-417 (codified at 15 U.S.C. § 68b, 21 U.S.C. §§ 301, 355, 360cc, and 35 U.S.C. §§ 156, 271, 282).

[2] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, ix (July 1998), *available at* <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf>.

[3] *Id.* at 32.

application to market a generic drug was filed.[4] Despite the benefits that Hatch-Waxman was intended to achieve, the Generic Drug Study found that the Act contained loopholes that could be used to delay generic competition. Generic Drug Study at viii-xi, 57-58. For example, a brand-name drug manufacturer and a first generic applicant could use the Act's provisions to delay the introduction of any generic version of a drug. *Id.*

Based in part on the findings of its Generic Drug Study, the Commission testified before Congress on the operation of the Hatch-Waxman Act, including the important role that declaratory judgment actions by generic drug manufacturers play in eliminating such delays.[5] Congress adopted the Commission's two major recommendations in its recent amendments to Hatch-Waxman.[6] Commission staff have also conducted empirical economic analyses of competition in the

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[4] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* ("Generic Drug Study") (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[5] *See, e.g.,* Letter dated October 21, 2003, from FTC Chairman Muris to Sens. Gregg and Kennedy, Senate Committee on Health, Labor, Education and Pensions, 149 Cong. Rec. S15883-03, S15886 (Nov. 25, 2003); Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (August 1, 2003), *available at* <http://www.ftc.gov/os/2003/08/030801pharmtest.htm.>; Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (June 17, 2003), *available at* <http://www.ftc.gov/os/2003/06/030617 pharmtestimony.htm>.

[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) (hereinafter, "Medicare Amendments").

pharmaceutical industry.[7] The Commission has invested considerable resources in protecting competition in the pharmaceutical industry -- it has commenced law enforcement actions against both branded and generic drug companies that have, allegedly, used certain provisions of Hatch-Waxman to impede competition.[8]

This case could play an important role in furthering competitive pharmaceutical markets and in lowering health care cost. It will create the first appellate precedent regarding whether there is a justiciable "controversy" when a subsequent generic applicant sues a patent owner or a brand-name drug manufacturer for a declaratory judgment that a listed patent is invalid or not infringed. In particular, in evaluating whether there was a controversy, the district court failed to take account of 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.

This issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment action is, under certain circumstances, the only means by which a generic drug maker may be able to overcome the obstacle to entry created by actions of the brand-name manufacturer and the first generic applicant. If the district court's decision is upheld, it will enable first generic applicants and

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[7] *See, e.g.,* David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf.

[8] *See, e.g., Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order); *Abbott Labs.*, Docket No. C-3945 (May 22, 2000) (consent order); *Geneva Pharms., Inc.,* Docket No. C-3946 (May 22, 2000) (consent order).

brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug. This result undermines the purposes of Hatch-Waxman and will deprive consumers of the benefits of full generic competition. Thus, the Commission has an interest in this case, and respectfully submits this *amicus* brief.

STATEMENT OF THE ISSUES PRESENTED

1) Whether the district court applied the proper standard in evaluating whether there was an actual controversy between the parties.

2) Whether there is a controversy sufficient to give the court jurisdiction over Teva's declaratory judgment action.

STATEMENT OF THE CASE

A. The Hatch-Waxman Act

The Hatch-Waxman Act seeks to encourage research and development of new drugs, while speeding the introduction of generic drugs. *See* H.R. Rep. No. 98-857(I), at 14-15. The Act furthers the latter goal by permitting manufacturers seeking FDA approval to market generic drugs to submit "Abbreviated New Drug Applications" ("ANDAs") to substantially shorten the time needed to obtain marketing approval. 21 U.S.C. § 355(j); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

The Act also seeks to promote the orderly and expeditious resolution of patent disputes between brand-name drug manufacturers and generic manufacturers by

creating a patent listing and certification procedure. *See* 21 U.S.C. § 355(j). Under this mechanism, a brand-name drug manufacturer must submit to the FDA information on any patent that claims certain aspects of an approved drug and is a patent for 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." 21 U.S.C. § 355(b)(1). The FDA's listing of such patents is known as the "Orange Book." If a generic firm (an "ANDA applicant") seeks FDA approval for a generic version of a brand-name drug before the expiration of any of the patents listed in the Orange Book, it may file a certification declaring that the patents are invalid or will not be infringed by the drug (a "Paragraph IV certification"), and notify the brand-name manufacturer of the certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Key provisions of Hatch-Waxman actively facilitate commencement of litigation concerning listed patents prior to generic marketing. *See* H.R. Report No. 98-857(I), at 28. First, Congress expressly provided that the filing of an ANDA containing a Paragraph IV certification constitutes an act of infringement, thus assuring that pre-marketing suits are available. 35 U.S.C. § 271(e)(2)(A); *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). Second, Congress encouraged the prompt commencement of such litigation. If a brand-name manufacturer (or patent owner) sues the generic manufacturer within 45 days of receipt of a Paragraph IV certification, FDA is barred, for up to 30 months, from approving the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Otherwise FDA may grant

immediate approval. *Id.* In addition, although the statute bars the generic manufacturer from bringing a declaratory judgment action during that 45-day period, it is free to do so thereafter. 21 U.S.C. § 355(j)(5)(C).

Finally, 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." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II). Under the 1984 version, a court "decision" included any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise, including dismissals with prejudice. *See, e.g., Minnesota Mining and Mfg. Co. v. Barr Labs., Inc.,* 289 F.3d 775, 778, 780 (Fed. Cir. 2002); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1008-1010 (D.C. Cir. 1999) (holding that, where a brand-name drug manufacturer (or the patent owner) covenants not to sue ANDA applicant for infringement, dismissal of ANDA applicant's declaratory judgment action for lack of subject matter jurisdiction has sufficient preclusive effect to qualify as a court "decision").

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.

B. Hatch-Waxman Act Experience and Congressional Response

Although Congress intended Hatch-Waxman to promote competition, several of its provisions, including the 180-day exclusivity period, proved susceptible to strategies to delay generic competition. In certain instances, first ANDA applicants entered into agreements with brand-name drug manufacturers that had the effect of "parking" the 180-day period. Such agreements can delay the commencement of the 180-day period and create a bottleneck that benefits only the brand-name manufacturer and the first ANDA applicant, to the detriment of subsequent ANDA applicants and consumers. *See* FTC Generic Drug Study at vii-viii, 34, 57, 63.

Brand-name manufacturers and first ANDA applicants can create such a bottleneck if the first ANDA applicant agrees to refrain from entering the market for some period of time, and if the brand-name firm forgoes suing subsequent ANDA applicants. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until 180 days after the first ANDA applicant enters, or until the relevant listed patents expire, or until a subsequent ANDA applicant can itself trigger the running of the 180-day period. *Id.* at vii; 57. A subsequent ANDA applicant may have a strong non-infringement defense (*e.g.*, it has done a better job of designing around the patent) capable of being decided on summary judgment and

affirmed on appeal substantially before the date the first ANDA applicant agreed to enter the market. Nevertheless, the brand-name firm and first ANDA applicant's actions still could delay that applicant from entering the market. The only way that a subsequent ANDA applicant can relieve this bottleneck would be to obtain a court decision through a declaratory judgment action.[9]

The impact of such delays is greatest when the first ANDA applicant and the brand-name manufacturer agree to a substantial delay of the date on which the first ANDA applicant enters the market. This postpones consumer access to *any* lower-priced generic version of the drug. *See* Generic Drug Study at 57, 62-63. But even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because competition among generic manufacturers has a strong impact on the price of a drug. One study found that, as the number of approved generic versions of a drug increased from one to ten, the average price for the generic version fell from 60% to 34% of the price for the brand-name version. R. Caves, *et al.*, *Patent Expiration, Entry and Competition in the U.S. Pharm. Indus.*, Brookings Papers on Economic Activity: Microeconomics, 36, table 9 (1991). For a drug like Zoloft, which had $2.7 billion in sales in 2002,[10] the cost to consumers of delaying additional generic entry would be substantial indeed.

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[9] Even if no bottleneck exists, declaratory judgment actions serve an important role because the Generic Drug Study showed that no generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book. Generic Drug Study at vii.

[10] *See* Pfizer, 2002 Annual Report, *available at* <http://www.pfizer.com/are/investors_reports/annual_2002/p2002ar24_25_26_27a.htm>.

In 2003, Congress amended Hatch-Waxman (the Medicare Amendments), in large part to "close loopholes in the law * * * ." 149 Cong. Rec. S15670-03, S15745 (Nov. 24, 2003) (statement of Sen. Schumer). Among other things, one of Congress's goals was to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Id.*

Congress sought to eliminate this bottleneck in two ways. First, Congress strengthened the original Act's declaratory judgment provisions by explicitly directing the courts to hear declaratory judgment actions by ANDA applicants "to the maximum extent permitted by the Constitution." *Id.*; Medicare Amendments, § 1101(d)(2), amending 35 U.S.C. § 271(e) ("[T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person * * * for a declaratory judgment that such patent is invalid or not infringed").

Second, Congress created a number of "forfeiture events" that cause a first ANDA applicant to lose the 180-day exclusivity. Medicare Amendments, § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv). If a subsequent ANDA applicant resolves the patent disputes that afforded the first ANDA applicant its exclusivity -- through, for example, a court decision, a court-entered settlement that the patents are invalid or not infringed, or a withdrawal of the patents by the brand-name manufacturer -- then the first ANDA applicant must bring its generic version to market within 75 days or forfeit the exclusivity. Medicare Amendments,

§ 1101(a)(2), amending 21 U.S.C. § 355(j)(5)(C).[11] These provisions by themselves, however, do not eliminate the problem of bottlenecks unless subsequent ANDA applicants can bring declaratory judgment actions to seek court decisions of invalidity or non-infringement of listed patents.[12]

C. The Present Litigation

This case arises from the efforts of Teva Pharmaceuticals USA, Inc., to gain FDA approval to market a generic version of Pfizer's sertraline hydrochloride drug. Pfizer has marketed the drug under the trade name Zoloft since 1992 for the treatment of mood and anxiety disorders. Pfizer submitted several patents for listing in the Orange Book for the drug, including U.S. Patent No. 4,356,518 ('518 patent), which expires in December 2005, and U.S. Patent No. 5,248,699 ('699 patent), which expires in September 2010. Pfizer also holds a six-month pediatric exclusivity for the drug, extending its exclusive rights to June 2006.

In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as Ivax, submitted an ANDA to market a generic sertraline hydrochloride drug. Ivax filed a "Paragraph

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[11] Congress counterbalanced these additional forfeiture events by providing that a "decision of a court" that can trigger forfeiture must be either an appellate decision or an unappealed district court decision. Medicare Amendments, § 1102(a)(2); 21 U.S.C. § 355 note. Congress, however, left unchanged the *type* of "decision" (*e.g.*, a substantive decision or dismissal with preclusive effect) that would forfeit the exclusivity. *Id.* Congress made this definition retroactive and it applies to this litigation.

[12] We take no position on the general applicability of the amendments to the present case; rather we show below that the district court erred, even assuming that the amendments are not applicable. Unless otherwise indicated, all references to the Hatch-Waxman Act are to the 1984 version.

III certification" with respect to the '518 patent (indicating that it will not enter the market until June 2006), but filed a Paragraph IV certification with respect to the '699 patent (indicating that the patent was invalid or Ivax's drug would not infringe the patent). Pfizer sued Ivax for patent infringement within 45 days, but the parties settled the dispute. Pursuant to that settlement, Pfizer granted Ivax a license under the '699 patent to manufacture generic sertraline hydrochloride commencing in June 2006 in exchange for royalty payments based on Ivax's sales.

In July 2002, Teva filed its ANDA. Teva also filed a Paragraph III certification to the '518 patent, and a Paragraph IV certification that it would market a different crystalline form of sertraline hydrochloride than the one claimed by the '699 patent or that the patent was invalid. Pfizer did not sue Teva, and also refused Teva's request for a covenant not to sue. Thus, Teva brought the present action for a declaration of non-infringement or invalidity of the '699 patent.[13] Pfizer moved to dismiss, arguing that the court lacked subject matter jurisdiction because there was no actual controversy between the parties. The court granted the motion on the basis that Teva had not demonstrated a reasonable apprehension that Pfizer would bring an infringement action against it. Accordingly, the court concluded that Teva's

[13] Dr. Reddy's Laboratories ("DRL") also submitted an ANDA to market generic sertraline hydrochloride. Like Ivax, it did not contest the '518 patent, but contended that its marketing of a generic would not infringe the '699 patent. Pfizer took no action within 45 days and DRL sought a declaratory judgment that its marketing of the generic drug would not infringe the '699 patent. The court dismissed DRL's action for lack of jurisdiction because it was "not fully persuaded" that the declaratory judgment involved a case or controversy. *Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, 2003 U.S. Dist. LEXIS 24351 (D.N.J. 2003).

complaint presented no case or controversy and dismissed the complaint for lack of jurisdiction.

SUMMARY OF THE ARGUMENT

Declaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime. These actions permit subsequent ANDA applicants to eliminate the bottlenecks that delay them from entering the market. Indeed, it would be contrary to the purpose of the Act to delay market entry by later applicants where the brand-name manufacturer and first ANDA applicant are involved in protracted litigation, or have settled their litigation without resolving the issues of validity or infringement.

The present suit involves precisely such an action. Here, the district court erred in assessing whether there was an actual controversy sufficient to create jurisdiction because it failed to consider Teva's injury (as a subsequent ANDA applicant) and Pfizer's conduct (as a brand-name manufacturer) within the context of Hatch-Waxman. Instead, it narrowly focused on whether Teva faced a reasonable apprehension of suit by Pfizer. That focus is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market. If this were a "classic" non-Hatch-Waxman case, Pfizer's conduct would not create a controversy. But because of Hatch-Waxman, Pfizer's actions create a legal barrier that, absent judicial intervention, delays Teva and other subsequent ANDA applicants from marketing a product. (Part I, *infra*.)

Properly analyzed, Teva's action involves an actual controversy under Article III of the Constitution. First, Teva has a direct stake in the outcome of the litigation, which is the only means (within Teva's control) whereby it can avoid the injury it suffers from the delay in bringing its product to market. Second, that injury is traceable to Pfizer's conduct with respect to the '699 patent -- not simply in obtaining and listing that patent with the FDA, but also settling its suit with the first ANDA applicant (Ivax), failing to bring suit against Teva, and refusing Teva's request for a covenant not to sue. Third, a favorable (and prompt) decision will redress Teva's injury because if it prevails, it can gain FDA approval to market its product as soon as June 2006. (Part II.A, *infra*.)

It would be inappropriate for the district court as a matter of discretion to decline jurisdiction, because actions by subsequent ANDA applicants such as Teva directly serve Hatch-Waxman's goals. If subsequent ANDA applicants cannot bring such cases, brand-name drug manufacturers and first ANDA applicants will have the ability to "park" the 180-day exclusivity period. They could thus delay *any* generic applicant from entering the market. Finally, exercising jurisdiction over this action does not force a lawsuit on a "quiescent" patent-owner. Pfizer has engaged in a course of conduct that, under the Hatch-Waxman scheme, preserves the bottleneck that delays Teva (and any subsequent ANDA applicant) from bringing its product to market. (Part II.B, *infra*.)

This court should find that the district court has jurisdiction, not only because doing so could prevent injury to Teva, but also because consumers for sertraline

hydrochloride could benefit. Moreover, a favorable decision by this Court could also result in gains for consumers of other drugs, where competition may be limited if generic companies are unfairly blocked from entering the market.

ARGUMENT

I. THE DISTRICT COURT APPLIED AN INAPPROPRIATE TEST WHEN IT ANALYZED WHETHER TEVA'S DECLARATORY JUDGMENT ACTION INVOLVED AN ACTUAL CONTROVERSY

When the district court dismissed Teva's declaratory judgment action for lack of jurisdiction, it woodenly applied a test that is ill-suited to analyze whether a controversy exists between a subsequent ANDA applicant and a brand-name drug manufacturer concerning listed patents. In particular, the test applied by the court failed to recognize that Teva is injured by Pfizer's actions that delay it from marketing its product. As this Court has recognized, a proper analysis of whether there is an "actual controversy" that can give rise to a declaratory judgment requires careful scrutiny, in light of general principles of justiciability under Article III of the Constitution. Such an analysis must take into account the practical circumstances facing the parties, including the legal and regulatory context in which they operate, and must assess whether, under the totality of the circumstances, there is a real and immediate "controversy." *Fina Oil and Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Had the court below conducted such an analysis, it would have recognized that there is indeed a live controversy between Teva and Pfizer regarding the '699 patent, involving concrete injury to Teva that can be redressed by declaratory relief.

Teva seeks a remedy that, pursuant to the Declaratory Judgment Act, may be invoked by a party "[i]n a case of actual controversy" within the jurisdiction of a federal court. 28 U.S.C. § 2201(a). As this Court has explained, the "actual controversy" requirement of 28 U.S.C. § 2201(a) parallels the "case or controversy" requirement of Article III of the Constitution. *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996), *citing Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-42 (1937). To satisfy the Article III requirement, the party seeking a declaratory judgment must show: (1) that it suffered an "injury in fact" -- an invasion of a judicially cognizable interest which is "concrete and particularized," and "actual or imminent, not conjectural or hypothetical"; (2) that there is a "causal connection between the injury and the conduct complained of" -- the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it is "likely," as opposed to merely speculative, "that the injury will be redressed by a favorable decision." *Bennett v. Spear*, 520 U.S. 154, 163-65, 167 (1997); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003). Because, in the declaratory judgment context, the "injury-in-fact" frequently has not yet occurred, the court must determine whether the parties have "adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 279, 280 (6th Cir. 1997) (*citing Golden v. Zwickler*, 394 U.S. 103, 108 (1969)).

To apply these requirements to patent suits, this Court frequently has employed

a "pragmatic" two-part test. *EMC Corp.*, 89 F.3d at 811-12. This test requires: "(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 activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). This Court has cautioned that satisfaction of this two-part test "is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action." *Fina Oil*, 123 F.3d at 1470. 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." *Id.*; *see also Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25-26 (1st Cir. 2001) ("a certain controversy renders the 'reasonable apprehension' question irrelevant").

The district court incorrectly analyzed whether a controversy existed between Pfizer and Teva by mechanically applying the first prong of the test, without taking into account the specific regulatory context of the Hatch-Waxman regime. This Court has stressed that "[t]here is no simple rule that addresses all shades of relationships between disputants." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). "'The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.'" *Gen-Probe, Inc. v. Vysis, Inc.*, 359

F.3d 1376, 1379-80 (Fed. Cir. 2004), *quoting Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Thus, a court must resolve the issue on the "'totality of the circumstances.'" *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991), *quoting Maryland Cas. Co.*, 312 U.S. at 272. The district court failed to examine the totality of the circumstances because it ignored the impact of Hatch-Waxman on the parties.

In a "classic patent declaratory judgment suit," the ordinary two-part test is appropriate because it captures all the elements of a controversy under Article III. *Fina Oil*, 123 F.3d at 1470. Of particular relevance to this case, the first part of the test, which considers the likelihood that a patentee will actually commence an infringement suit, usually provides a good assessment of whether the plaintiff faces "injury in fact," and whether the issues have ripened sufficiently for judicial review. *See, e.g., EMC Corp.*, 89 F.3d at 811. Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In the absence of the serious prospect of an infringement action, there is no immediate threat of legal injury, no need to invoke the power of the court and, thus, no actual controversy. *See, e.g.*, *Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153, 1158-61 (Fed. Cir. 1996), *rev'd on other grounds by Nobel Pharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998); *BP Chems.*, 4 F.3d at 977-78.[14]

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[14] For example, even if the competitor faces the loss of customers or business partners who are wary of the patentee's portfolio, the competitor may resolve these harms extrajudicially -- such as by agreeing to indemnify the customers or identifying other business partners.

In contrast, in 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. As discussed above, ANDA applicants cannot legally market a drug absent FDA approval. A brand-name drug manufacturer can delay subsequent ANDA applicants from obtaining this approval if it settles its patent disputes with the first applicant, and does not sue subsequent applicants for infringement of its listed patents. This delay directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market for the drug. The only plausible way for subsequent ANDA applicants to remedy this injury is through judicial action concerning the patents listed for the drug.

For example, under Hatch-Waxman, Teva is subject to a direct legal impediment that prevents it from marketing its product even if Pfizer does not sue to enforce its '699 patent. Teva, the subsequent ANDA applicant, has sought FDA approval to market its generic sertraline hydrochloride drug immediately after the '518 patent and the relevant pediatric exclusivity expire in June 2006. But, as a result of the entirety of Pfizer's conduct regarding the '699 patent -- including its listing in the Orange Book, its settlement of its lawsuit with the first ANDA applicant, its failure to sue Teva, and its refusal to grant Teva a covenant not to sue -- the FDA is

precluded from granting final approval to Teva.[15] In particular, the FDA may not grant approval to Teva or any other ANDA applicant (prior to the expiration of the '699 patent in 2010) until Ivax (the first applicant) has marketed its product for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Unless Teva (or another generic applicant) secures an adjudication of its dispute regarding the '699 patent, 21 U.S.C. § 355(j)(5)(B)(iv)(II), it will face a certain delay of at least 180 days before it can enter the market -- or perhaps more, if Ivax delays for any reason.[16] As noted above, the 180-day delay itself has major economic consequences for a drug such as the one at issue here. Thus, unlike the classic patent declaratory judgment suit, here Teva suffers legal injury independent of the threat of an infringement action, as a result of actions already taken by Pfizer.

The prospect of such injury, in the near future and not based on mere speculation, is fully adequate to present an actual controversy. *See, e.g. Nat'l Rifle Ass'n*, 132 F.3d at 280. Indeed, several circuit judges have explicitly suggested that an apprehension of suit may not be required to exercise jurisdiction over a declaratory judgment action by a subsequent ANDA applicant. For example, a District of Columbia Circuit panel stated that:

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[15] The Commission does not suggest that Pfizer's conduct is illegal, only that it causes injury sufficient to create an actual controversy.

[16] In *Dr. Reddy's Labs. v. Pfizer, supra,* the court treated the 180-day period as if it were Ivax's absolute entitlement, with which a subsequent ANDA filer should not interfere. *Id.* at *24-25. It is, however, not an entitlement, because, as this Court has recognized, it can be triggered as a result of a court decision brought by a subsequent ANDA applicant. *Minnesota Mining*, 289 F.3d at 780.

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

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1073-74 (D.C. Cir. 1998). Similarly, Judge Gajarsa of this Court also recently opined that "the inability to market a product without a court decision may create sufficient case or controversy for the purposes of a declaratory judgment action." *Minnesota Mining*, 289 F.3d at 791 (Gajarsa, J., concurring in judgment). Thus, the two-part test applied by the district court, which focused solely on the likelihood of enforcement, did not capture the injury that Teva suffers from the bottleneck that delays it from marketing its product. That is, the district court failed to follow this Court's admonition to consider the "totality of the circumstances." *Gen-Probe*, 359 F.3d. at 1379-80. Because the district court's holding that it lacked jurisdiction was based on an inappropriate test, that decision should be reversed.

II. THE DISTRICT COURT HAS JURISDICTION OVER TEVA'S DECLARATORY JUDGMENT ACTION

A. Teva's case involves an actual controversy

Because Teva's complaint involves a real and immediate controversy, the district court had subject matter jurisdiction pursuant to Article III of the Constitution and this Court should remand the case to the district court for resolution of the merits of Teva's claims.

Teva's declaratory judgment action satisfies all the elements of an actual

controversy under Article III. As this Court has observed, these elements are "injury in fact, connection between the challenged conduct and the injury, and redressability of the injury by the requested remedy." *Allergan*, 324 F.3d at 1331. A party that has suffered "injury in fact" has been adversely affected or aggrieved and has a direct stake in the outcome of litigation. Lost opportunities to compete and lost potential future profits have been held sufficient to constitute "injuries" for the purposes of Article III. *E.g., Northeastern Fla. Chapter, Associated Gen. Contractors of America v. City of Jacksonville*, 508 U.S. 656, 664-68 (1993); *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160-61 (1981).

Without question, Teva has a direct stake in the outcome of its case against Pfizer. If it prevails in obtaining a declaration that its generic sertraline hydrochloride drug does not infringe the '699 patent (or that the '699 patent is invalid), such a declaration will commence the running of the 180-day period and, at the end of that period, the FDA can approve Teva's ANDA. Further, if Teva gains such a decision before December 2005,[17] then Teva could then enter the market in June 2006, at the same time Ivax is scheduled to enter. Absent such a decision, Teva (and every other ANDA applicant) instead must wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that Teva can advance the date of the approval of its product is

[17] As explained above, the decision must be one "from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." § 1102(b)(3) of the Medicare Amendments (21 U.S.C. § 355 note).

through this litigation. Absent this action, Teva suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days.

There is a clear connection between Pfizer's actions and Teva's injury. 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 had the opportunity to gain access to the market during the 180-day period. 21 U.S.C. § 355(j)(5)(B)(ii). Thus, Pfizer's actions cause Teva to suffer the financial loss from the delayed marketing of its generic sertraline hydrochloride. *See, e.g., Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-76 (1978).

Finally, a favorable decision on the merits of Teva's case will redress Teva's injury. If the Court reverses the district court's decision, it will restore Teva's opportunity to trigger the 180-day period to gain access to the market. If Teva prevails in establishing that it will not infringe the '699 patent or that the patent is invalid, then the FDA can approve Teva's ANDA. If this happens promptly, Teva will not be delayed in bringing its product to market, and it (and other ANDA applicants) will not have to forgo sales during the first 180 days after Ivax enters. *See, e.g., Watt*, 454 U.S. at 160-61; *Pac. Gas & Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n*, 461 U.S. 190, 201-02, n.15 (1983).

The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays Teva from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an

infringement suit against Teva. The dispute is ripe because these actions cause immediate injury to Teva greater than even an *express* threat of suit in a classic patent case.[18] Properly analyzed, and considering the reality of Teva's circumstances, Teva's complaint satisfies all elements of an actual controversy.

B. Discretionary dismissal of Teva's action is not appropriate

Although this Court has held that courts normally have discretion to decline jurisdiction over a declaratory judgment action even where there is an Article III controversy, *EMC Corp.,* 89 F.3d at 810, it would be inappropriate for a district court to do so here. Congress intended that courts take jurisdiction over declaratory judgment actions filed by subsequent ANDA applicants such as Teva.[19] Indeed, the Hatch-Waxman Act can only achieve its goals of (1) speeding access to generic drugs, *Eli Lilly & Co.*, 496 U.S. at 676, and (2) enabling early resolution of patent disputes, H.R. Report No. 98-857(I), at 28 (1984), if declaratory judgment actions are available to subsequent ANDA applicants.

Although this Court has not had occasion previously to address the issue

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[18] The analysis of whether an actual controversy exists encompasses the doctrine of ripeness. An issue is ripe if it is fit for judicial decision and if withholding consideration will cause hardship. *Cedars-Sinai Medical Center v. Watkins*, 11 F.3d 1573, 1580-81 (Fed. Cir. 1993). Here the issue is clearly fit for judicial decision because the issue before this Court is legal in nature and no further factual development is necessary. Also, withholding decision would harm Teva -- absent favorable resolution of its action, harm to Teva is certain.

[19] Indeed, when it amended the Hatch-Waxman Act, Congress specifically provided that courts should exercise jurisdiction over actions such as this one "to the extent consistent with the Constitution * * *." Medicare Amendments § 1101(d), *amending* 35 U.S.C. § 271(e).

presented here, it has generally recognized that declaratory judgment actions by a subsequent ANDA-applicant are essential to the Hatch-Waxman Act's goal of speeding access to generic drugs:

> [We agree] that § 355(j)(5)(B)(iv)(II) is triggered by the termination of an action commenced by the second ANDA filer * * * . [I]t would be contrary to the very purpose of the Act to allow the first filer to block market entry of other generic manufacturers because the first filer is involved in protracted litigation.

Minnesota Mining, 289 F.3d at 780 (internal quotation marks and citation omitted). Further, exercising jurisdiction here does not force a lawsuit on the sort of "quiescent" patentee that this Court has sought to protect. *See EMC Corp.*, 89 F.3d at 812. Pfizer brought and settled one lawsuit, thereby creating the roadblock that Teva is seeking to lift, it declined to sue Teva, and it refused to grant Teva a covenant not to sue. Absent jurisdiction over Teva's declaratory judgment action, Teva is precluded by Pfizer's conduct from entering the market as soon as it would otherwise be able, and consumers are deprived of the benefits of increased generic competition.[20] Moreover, unless there is jurisdiction in cases such as this one, subsequent ANDA applicants will be powerless to stop brand-name manufacturers and first ANDA applicants from parking the exclusivity period far beyond 180 days.[21]

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[20] Pfizer could, of course, moot the controversy by granting Teva's request for a covenant not to sue.

[21] There is nothing in the district court's decision that suggests it would have found jurisdiction if the agreement between Pfizer and Ivax had (perhaps in exchange for a payment from Pfizer to Ivax) provided that Ivax would forgo marketing its drug, for example, until 2008, 2009, or until 180 days before the '699 patent expires in 2010. If Ivax and Pfizer had done so, they could "park" the 180-day exclusivity and delay the entry of *any* generic sertraline hydrochloride drug for a matter of years.

Exercising jurisdiction over Teva's action also serves the second Hatch-Waxman goal of allowing early resolution of patent disputes. *See, e.g.,* H.R. Report No. 98-857(I), at 28 (1984) (stating that the patent certification provisions "permit[] the commencement of a legal action for patent infringement before the generic drug maker has begun marketing"). The Hatch-Waxman Act specifically contemplates actions brought by brand-name manufacturers against initial and subsequent ANDA applicants in order to resolve patent disputes before generic entry and to limit the uncertainty over potential liability that would otherwise attend generic entry. 21 U.S.C. § 355(j)(5)(B)(iii); *see, e.g.*, 130 Cong. Rec. 24427 (Sept. 6, 1984) (Statement of Rep. Waxman); *see also Warner-Lambert Co.*, 316 F.3d at 1357, 1365. Nothing in Hatch-Waxman dictates that only a brand-name drug manufacturer can initiate an action to protect its patent but that an ANDA applicant cannot protect its interests by bringing what is essentially the same action. Such a result would hinder early resolution of relevant patent disputes, where, as here, the brand-name manufacturer's interests may be served by delaying resolution of the dispute.

CONCLUSION

For the foregoing reasons the Federal Trade Commission respectfully urges this Court to reverse the district court's dismissal of the present action, and to remand the matter for resolution of the merits.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B). It contains 6971 words.

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