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'S COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

JOHN D. GRAUBERT
Acting General Counsel

SUSAN A. CREIGHTON
Director, Bureau of Competition

JOHN F. DALY
Deputy General Counsel for Litigation

LORE A. UNT
Counsel for Intellectual Property

LAWRENCE DeMILLE-WAGMAN
Attorney
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
(202) 326-2448

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

CASES **PAGE**

STATUTES

MISCELLANEOUS

STATEMENT OF CONFLICT

The decision of the panel majority conflicts with the following decisions of the Supreme Court and this Court: *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270 (1941); *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997); and *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988).

STATEMENT OF INTEREST

The Federal Trade Commission is an independent federal agency that seeks to promote the efficient functioning of the marketplace and to protect consumer interests. The Commission has significant expertise in the pharmaceutical industry and the Hatch-Waxman Act. The Commission has, *inter alia*, completed a 2002 study of generic drug entry under the Hatch-Waxman Act;[1] testified before Congress on the competitive effects of the Act;[2] and commenced law enforcement actions against drug companies that have, allegedly, used portions of the Act to impede competition.[3] A declaratory judgment action, such as the one brought by Teva, could

---

[1] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* ("Generic Drug Study") (July 2002) at viii-xi, 57-58, *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[2] *See, e.g.*, 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.>.

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

play an important role in furthering competitive pharmaceutical markets and in lowering health care costs. Accordingly, the Commission has an interest in this case, and respectfully submits this *amicus* brief in support of Teva's combined petition for rehearing and rehearing *en banc*.[4]

STATEMENT OF THE ISSUE PRESENTED

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

STATEMENT OF THE CASE

1. 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 (1984). The Act attempts to speed the introduction of generic drugs by expediting the generic drug approval process, and by promoting the resolution of patent disputes between brand-name and generic drug manufacturers. The Act requires brand-name manufacturers to submit to the FDA information on certain patents that claim its drug. 21 U.S.C. § 355(b)(1). These patents are listed in what is known as the "Orange Book." A generic firm seeking FDA approval for a generic version of a brand-name drug before the expiration of such patents may certify that the patents are invalid or will not be infringed by its proposed generic (a "Paragraph IV certification"). The Act facilitates litigation concerning such patents by providing that the filing of an application for a generic drug containing a Paragraph IV

[4] On March 31, 2004, the Commission filed a brief as *amicus curiae* in support of Teva's appeal to this Court.

certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

The Hatch-Waxman Act also encourages generic manufacturers to challenge patents by providing that the first generic applicant to file an application containing a Paragraph IV certification may be eligible for a conditional 180 days of marketing exclusivity, during which the FDA may not approve subsequent generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). 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) the date of a court decision holding that the patent at issue is invalid or will not be infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(I-II). If the first generic applicant triggers the 180-day period by promptly bringing its product to market, then it is permitted, for 180 days, to be the only generic competitor for the brand-name drug. If, however, another generic firm first obtains such a court decision and the first generic applicant does not or cannot market its product during the 180 days, the exclusivity lapses and the first generic has no exclusivity. *Id.*

The 180-day exclusivity period may be susceptible to strategies to delay generic competition. In some instances, a first generic applicant could enter into an agreement with the brand-name manufacturer. The generic applicant would agree to delay entering the market, and the brand-name firm would forgo suing subsequent generic applicants. Such an agreement has the potential to delay the commencement of the 180-day period, and to preclude the FDA from approving subsequent generic applicants. Such a bottleneck would benefit only the brand-name manufacturer and the first generic applicant, to the detriment of subsequent generic applicants and

consumers. *See* Generic Drug Study at vii-viii, 34, 57, 63. The only way that a subsequent generic applicant could relieve such a bottleneck would be to obtain a court decision holding that the patent is invalid or not infringed. Such a decision would trigger the 180-day period, at the close of which the FDA may approve subsequent generics.

2. This case arises from the efforts of Teva Pharmaceuticals USA, Inc., to preclude the formation of such a bottleneck, and to gain FDA approval to market a generic version of Pfizer's sertraline hydrochloride drug, which is marketed as Zoloft. Pfizer submitted several patents to the FDA for listing in the Orange Book regarding Zoloft, including U.S. Patent No. 4,356,518 ('518 patent), which effectively expires in June 2006, and U.S. Patent No. 5,248,699 ('699 patent), which expires in September 2010. In 1999, Ivax became the first manufacturer to apply to the FDA to market generic sertraline hydrochloride. Ivax certified that it would not enter the market until June 2006, when the '518 patent expired. However, it filed a Paragraph IV certification with respect to the '699 patent (indicating that the '699 patent was invalid or would not be infringed by Ivax's drug). Pfizer sued Ivax for patent infringement and the parties settled. 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.

In July 2002, Teva filed its application to market its generic sertraline hydrochloride. It filed a Paragraph IV certification with respect to the '699 patent indicating, just as Ivax indicated, that the '699 patent was invalid or would not be

infringed by Teva's generic. However, pursuant to Hatch-Waxman, the FDA could not approve Teva's generic until Ivax had marketed its generic for 180 days, or until 180 days after a court determination that the '699 patent was invalid or would not be infringed. But Pfizer did not sue Teva. Thus, Teva brought the present action for a declaration of non-infringement or invalidity of the '699 patent. Pfizer moved to dismiss, arguing that the court lacked subject matter jurisdiction because there was no actual controversy between the parties. The district court granted the motion on the basis that Teva had not demonstrated a reasonable apprehension that Pfizer would bring an infringement action against it, and had therefore presented no case or controversy. The panel (per Judge Schall) affirmed the district court's decision. Judge Mayer dissented.

ARGUMENT

THE PANEL MAJORITY'S ANALYSIS OF WHETHER TEVA'S DECLARATORY JUDGMENT ACTION INVOLVED AN ACTUAL CONTROVERSY CONFLICTS WITH OTHER DECISIONS OF THIS COURT

This Court has recognized that a proper analysis of whether there is an "actual controversy" that can give rise to a declaratory judgment action requires careful scrutiny, taking into account the practical circumstances facing the parties. This analysis must consider the legal and regulatory context in which the parties 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 panel majority 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 only by the declaratory relief it sought.

The "actual controversy" requirement of the Declaratory Judgment Act, 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). To satisfy the Article III requirement, the party seeking a declaratory judgment must show: (1) injury in fact; (2) a causal connection between the injury and the conduct complained of; and (3) that it is likely that the injury will be redressed by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 163-65, 167 (1997). 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 what it referred to as a "pragmatic" two-part test. *EMC Corp.*, 89 F.3d at 811-12. This test requires: (1) an explicit threat by the patentee that the declaratory plaintiff will face an infringement suit; and (2) present activity that could constitute infringement. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). But as Judge Mayer noted in dissent, this Court has "never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy." Dissent at 2, *citing Arrowhead Indus. Water, Inc. v. Ecolochem,*

Inc., 846 F.2d 731, 735-36 (Fed. Cir. 1988). 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). As the Supreme Court held, "[T]he 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." *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *see Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379-80 (Fed. Cir. 2004).

Despite the need for flexibility when determining the existence of a case or controversy, the panel majority clearly believed that the two-part test was "a constitutional requirement." Opinion at 19. In a "classic patent declaratory judgment suit," the ordinary two-part test may well be appropriate because it captures all the elements of a controversy under Article III. *Fina Oil*, 123 F.3d at 1470. 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." *See, e.g., EMC Corp.*, 89 F.3d at 811. But in the Hatch-Waxman regime in which Teva is operating, Teva suffers direct legal injury and requires judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that Pfizer has already taken concerning its patents. As discussed above, Teva cannot legally market its drug absent FDA approval, and it cannot get that approval until either: 1) Ivax has marketed its generic version for 180 days; or

2) there has been a court determination that the '699 patent is invalid or will not be infringed. As a result of Pfizer and Ivax's settlement, those two companies have complete control over the first of those two avenues. The panel majority's decision blocks the second.

The panel majority stated that the harm Teva suffers does not constitute injury in fact because it "is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme." Opinion at 24. But the panel majority ignored that Hatch-Waxman itself effectively anticipates the sort of harm at issue here, and affords parties in Teva's position an avenue by which to obtain FDA approval. In particular, Hatch-Waxman has always recognized that generic applicants like Teva may avoid the bottleneck imposed by Pfizer and Ivax's agreement if they can obtain a court determination that the '699 patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (1984).[5] By precluding Teva from even seeking such relief, the panel majority's ruling not only ignores the reality of the harm Teva suffers, but conflicts with the policies underlying Hatch-Waxman.

Teva's injury -- delay in bringing its drug to market -- will occur in the near future and is not based on mere speculation. This injury is sufficient to create an actual controversy. *See, e.g., Nat'l Rifle Ass'n*, 132 F.3d at 280. As Judge Gajarsa opined, "[t]he inability to market a product without a court decision may create

---

[5] In the 2003 Medicare Modernization Act, Congress amended Hatch-Waxman and strengthened a generic applicant's ability to seek a declaratory judgment to prevent the exact harm that is occurring here. 21 U.S.C. § 355(j)(5)(C)(i)(II).

sufficient case or controversy for the purposes of a declaratory judgment action." *Minnesota Mining and Mfg. Co. v. Barr Labs. Inc.*, 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring in judgment). The test applied by the panel majority, which focused solely on the likelihood of affirmative steps by Pfizer to enforce its patent, does not capture the injury that Teva suffers.[6]

There is a clear connection between Pfizer's actions and Teva's injury. If Pfizer had not listed the '699 patent in the Orange Book and settled its litigation with Ivax, and if it had not declined to sue Teva, Teva would have had the opportunity to trigger Ivax's 180-day period of exclusivity and gain earlier access to the market. 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). 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. Had the panel majority properly analyzed Teva's circumstances, it would have realized that Teva's complaint satisfies all elements of

---

[6] Presumably, under the panel's ruling, Teva would not be able to show "injury in fact" even if Ivax (pursuant to agreement with Pfizer or otherwise) delays its entry into the market beyond the expiration date of the '699 patent. Such a delay would be of great benefit to Pfizer because it would extend the period within which it exclusively marketed sertraline hydrochloride. Indeed, Pfizer would have no incentive whatsoever to initiate a suit against Teva because the suit might give Teva access to the market.

an actual controversy, even if it does not satisfy its ordinary two-part test.

CONCLUSION

For the foregoing reasons, the Federal Trade Commission respectfully urges that rehearing or rehearing *en banc* be granted.

Respectfully submitted,

JOHN D. GRAUBERT
Acting General Counsel

SUSAN A. CREIGHTON
Director, Bureau of Competition

JOHN F. DALY
Deputy General Counsel for Litigation

LORE A. UNT
Counsel for Intellectual Property

_____

LAWRENCE DeMILLE-WAGMAN
Attorney
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
(202) 326-2448

CERTIFICATE OF SERVICE

I hereby certify that, on February 8, 2005, I served two copies of the Brief of Amicus Curiae Federal Trade Commission Supporting Appellant's Combined Petition for Rehearing and Rehearing En Banc on counsel for appellant and appellee by sending those copies by express overnight delivery to:

Henry C. Dinger, PC
Goodwin Procter LLP
Exchange Place
Boston, MA 02109

Steven J. Lee
Thomas J. Meloro
Kenyon & Kenyon
One Broadway
New York, New York 10004

Dimitrios T. Drivas
White & Case, LLP
11155 Avenue of the Americas
New York, New York 10036-2787

_____
Lawrence DeMille-Wagman