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

---

[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 comb

[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

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

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,*

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 b

[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).

[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

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