Appeal No. 04-1186

United States Court of Appeals

for the

Federal Circuit

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

– v. –

PFIZER INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS IN CIVIL ACTION NO. 03-10167, JUDGE RICHARD G. STEARNS

BRIEF OF *AMICUS CURIAE* GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITION OF TEVA PHARMACEUTICALS USA, INC. FOR REHEARING OR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

In accordance with Federal Circuit Local Rule 47.4, counsel for Generic Pharmaceutical Association certify that:

1. The full name of every party represented by me is: Generic Pharmaceutical Association.

2. The real party in interest represented by me is: Generic Pharmaceutical Association.

3. All parent corporations or publicly held companies that own 10 percent or more of the stock of a party or amicus represented by me are: None.

4. X There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the partners or associates that previously appeared in this case for Generic Pharmaceutical Association are:

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IDENTITY AND INTEREST OF AMICUS CURIAE

Amicus curiae Generic Pharmaceutical Association ("GPhA") represents companies devoted to making lower priced, high quality generic drugs available to patients and providers, thus assisting in the battle against rapidly growing health-care costs. Its members include manufacturers and distributors of finished generic drug products and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. Generic manufacturers invest millions of dollars in innovative research and development to bring to the public lower priced bioequivalents of brand name drugs. And GPhA members manufacture more than 90% of all affordable prescriptions dispensed in the United States, accounting for more than one billion prescriptions every year.

GPhA's interest in this case arises from the system created by the Hatch-Waxman amendments to the Federal Food, Drug and Cosmetic Act. Under Hatch-Waxman, before generic companies can obtain FDA approval, they must address patents owned or licensed by brand companies, often triggering infringement actions. Congress created the Hatch-Waxman infringement suit provision to ensure that patent validity and infringement issues are resolved quickly, and before patent expiration. This early-resolution mechanism is essential for getting generic drugs into the hands of the American public as quickly as possible, consistent with the legitimate patent rights of brand name drug companies.

GPhA has a critical interest in ensuring the appropriate administration of declaratory-judgment suits in cases such as this one. This is particularly true where, as here, the patentee has an economic incentive to delay bringing suit because such a delay creates uncertainty that forestalls generic competition. In this situation, a generic manufacturer should be able to initiate a declaratory suit to promptly resolve whether its proposed product will infringe the brand company's patent.

INTRODUCTION

Amicus curiae GPhA submits this brief in support of the request by plaintiff-appellant Teva Pharmaceuticals USA, Inc. ("Teva") that this appeal be reheard by the panel or reheard *en banc*. The majority opinion by the panel in this case will significantly delay generic pharmaceutical manufactures such as Teva from marketing their affordable drugs and, as a consequence, will reduce choices and increase the prices paid by the tens of millions of Americans who buy these products. The panel majority opinion also improperly creates a new constitutional requirement – under which a declaratory plaintiff must show a "reasonable apprehension of *imminent suit*" – that contravenes the precedent of both the Supreme Court and this Court. By raising its new test to a constitutional dimension, the majority's requirement frustrates Congress' intention in amending the Hatch-Waxman provisions to mandate that courts adjudicate patent disputes

that block the market entry of generic drugs.

This case does not present an abstract, hypothetical situation, but rather a concrete controversy between the parties that the court should resolve on its merits. Teva has already committed a technical act of infringement by filing its ANDA, *see* 35 U.S.C. § 271(e)(2), Pfizer has indicated that its patent "could reasonably be asserted" against such an ANDA filer, *see* 21 U.S.C. § 355(b)(1), and as the dissent here noted, "economics and common sense dictate that Pfizer may well bring suit," *see Teva Pharmaceuticals USA v. Pfizer*, 2005 U.S. App. LEXIS 1078, *54 (Fed. Cir. Jan. 21, 2005) (Mayer, J., dissenting). Moreover, generic pharmaceutical manufacturers in Teva's position suffer a real injury when their ability to obtain regulatory approval to market their product is delayed by a brand company such as Pfizer that chooses to keep its patent hanging over their heads. Congress has mandated that the courts *shall* adjudicate such controversies to the limits of the Constitution, which in this instance provides no shelter for Pfizer.

REASONS FOR REHEARING THIS APPEAL

I. The Panel Majority Decision Raises Exceptionally Important Issues By Imposing a New Constitutional Requirement That Frustrates Congress' Chosen Means to Address the Pressing Problem of High Drug Prices

One of the major issues facing this country today is the skyrocketing cost of health-care, which includes the growing cost of drugs. The 1984 Hatch-Waxman amendments and the 2003 Medicare Act amendments were informed by Congress'

understanding that high drug prices are an important problem. *See, e.g., Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (discussing the background of the Hatch-Waxman amendments). The declaratory judgment provision at issue here is central to the efficient development and approval of generic drugs under the auspices of the Hatch-Waxman amendments.

A. Hatch-Waxman is designed to increase generic competition by encouraging multiple patent challenges

An overriding purpose of the Hatch-Waxman amendments is to permit all eligible generics to get on the market as quickly as possible. The Congressional Budget Office has explained that:

> By making generic entry easier and less costly, the Hatch-Waxman Act helped increase the number of generic manufacturers producing the same drug. As the number of manufacturers rises, the average prescription price of a generic drug falls.

How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, at xiii (Cong. Budget Office, 1998). The Federal Trade Commission's *amicus curiae* brief to the panel in this case credits a study as showing that the average price for a generic version of a drug fell from 60% to 34% of the price for the brand-name version as the number of approved generic versions increased from one to ten. (Br. at 8.) Thus, in this case, first-filer IVAX may well provide generic sertraline product upon the expiration of Pfizer's compound patent, but competition will not be nearly as robust as it will be if

Teva's suit goes forward and is successful, opening the door for Teva to go to market. Other ANDA filers also wait in the wings, seeking to assert their right to market generic sertraline when the compound patent expires. *See Dr. Reddy's Labs. v. Pfizer*, 2003 U.S. Dist. LEXIS 24351 (D.N.J. July 8, 2003) (dismissing declaratory judgment action); *Apotex, Inc. v. Pfizer Inc.*, 2004 U.S. Dist. LEXIS 26232 (S.D.N.Y. Dec. 30, 2004) (same).

A first ANDA filer, such as IVAX here, does not have an absolute "right" to a period of exclusive generic marketing, much less a right which can be "parked" for future exploitation. To allow for the earliest competition and the lowest prices, Congress provided that a first ANDA filer's 180-day exclusivity period would be triggered by a court decision obtained by *any* ANDA filer declaring a challenged patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The statutory scheme precludes a first ANDA filer from "parking" its exclusivity if a second ANDA filer, such as Teva in this case, can quickly establish that it has a right to go on the market with its generic drugs. *See Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 789 (Fed. Cir. 2002) (Gajarsa, J., concurring) (explaining that "Congress wanted second ANDA filers to be able to manufacture their drugs quickly if they could prove noninfringement."). By precluding challengers such as Teva, Apotex, and Dr. Reddy's Laboratories from establishing the merits of their patent challenges, which would start the first ANDA filer's 180-day exclusivity

period, *see Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), the panel decision frustrates the statutory scheme and undermines much of the benefits of early competition resulting from multiple patent challenges.

B. The Medicare Amendments intended to expand declaratory judgment jurisdiction

In enacting the 2003 Medicare Act amendments to the Hatch-Waxman provisions, Congress intended that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." Conf. Rept. No. 108-391 at 836 (2003). The legislation specifically provides that courts "*shall,* to the extent consistent with the Constitution, have subject matter jurisdiction" in a declaratory judgment such as the present case. 35 U.S.C. § 271(e)(5) (emphasis added). Congress added the language providing that jurisdiction shall be exercised "to the extent consistent with the Constitution" simply to leave resolution of constitutional questions in the hands of the courts, not the legislature. The Act certainly does not evince any intent to require the two-part test applied by the panel majority.

II. The Panel Majority Decision Raises the Exceptionally Important Issue of Whether the Constitution Requires a Declaratory Judgment Plaintiff To Show a "Reasonable Apprehension of *Imminent Suit*" Even Where There is a Real and Substantial Controversy

GPhA respectfully submits that the panel majority opinion improperly elevated into a constitutional requirement the two-part declaratory judgment jurisdiction test used by this Court prudentially in patent cases. *See Teva v. Pfizer*, 2005 U.S. App. LEXIS 1078, *29 ("[W]e do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement."). This approach contravenes Supreme Court precedent. *See Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937) (providing criteria for evaluating whether a declaratory judgment suit satisfies the Constitution). Compounding its error, the panel majority improperly held that the "reasonable apprehension" part of this test is only met where there is an apprehension of "imminent suit." *See Teva v. Pfizer*, 2005 U.S. App. LEXIS 1078, *26. By reading this test into the Constitution, and by holding that a situation such as in the present case is not "imminent" enough to meet that test, the panel opinion unduly blocks generic manufacturers from the ability to challenge patents that are preventing them from being able to bring their lower-priced generic drugs to market.

As Judge Mayer recognized in dissent, this Court has never before held that the two-part test is a constitutional requirement. *See id.* at *43-44 (Mayer, J., dissenting). The *Aetna Life* criteria are met in situations such as in the present case because they involve a real and substantial controversy.

A. Both the "reasonable apprehension of suit" and "present activity" parts of this Court's prudential test are met in this case

There can be no serious question that a party in Teva's position faces a "reasonable apprehension" of being sued by Pfizer. Given that Pfizer's Orange Book listing tells the world of Pfizer's judgment that its patent could reasonably be asserted against an ANDA filer, given Pfizer's history of bringing patent suits (including against IVAX over the patent at issue here), and given that Pfizer has over two billion dollars in sales to protect, it is "common sense" (as Judge Mayer put it) that Teva should reasonably apprehend suit. *See id.* at *50, *54.

Neither the panel majority nor Pfizer dispute that the "present activity" part of the test is met by Teva's ANDA filing, which itself constitutes a technical act of infringement. *See id.* at *21. Essentially, the majority opinion here incorrectly conflates the two-parts of this Court's traditional test into a requirement that the "reasonable apprehension" be not just of a suit, but of an "*imminent* suit." The majority failed to recognize that the concept of "imminence" is captured by the "present activity" part of the test (which admittedly was established by Teva). Correcting the panel majority's erroneous constitutional requirement of "imminent suit," which presumably must now be met by all declaratory judgment plaintiffs, is exceptionally important.

B. Teva has suffered an injury in this real and substantial controversy which admits of specific relief

The generic exclusivity provisions of Hatch-Waxman, as applied to the facts of this case, are more than enough to satisfy the Constitution's "case or controversy" requirement. Assuming Teva prevails on the merits in this case, it will result in a judicial decision triggering Ivax's purported exclusivity period and eliminating the bottleneck which Pfizer's settlement with Ivax was designed to foster. Thus, Teva's need to obtain a court decision to open the bottleneck is enough to create declaratory judgment jurisdiction. *See id.* at *52 (Mayer, J., dissenting) ("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."); *Minnesota Mining & Manufacturing*, 289 F.3d at 791 (Gajarsa, J., concurring) ("the inability to market a product without a court decision may create sufficient case or controversy"); *Mova*, 140 F.3d at 1073-74 n.18 ("It is possible 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.").

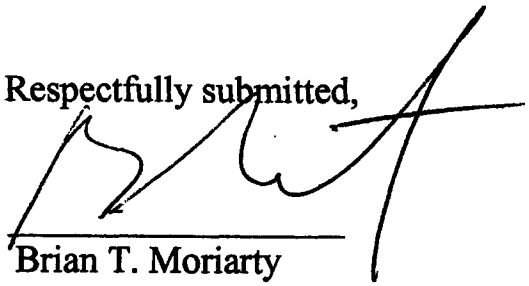
Whether or not this Court's two-part test is co-extensive with the Constitution's "case or controversy" requirement so as to preclude jurisdiction where a party has suffered a cognizable injury — such as Teva suffered as a result of the Hatch-Waxman framework and Pfizer's conduct in settling with Ivax — is

an exceptionally important issue which the panel should rehear or the Court should rehear *en banc*.

CONCLUSION

For these reasons, GPhA respectfully submits that this Court should grant Teva's request for the panel to rehear this case or for the case to be reheard en banc.

Respectfully submitted,



February 11, 2004

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