Appeal 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.

Appeal from the United States District Court for the District of Massachusetts in Case No. 03-CV-10167, Judge Richard G. Stearns

OPPOSITION OF DEFENDANT-APPELLEE TO COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

DIMITRIOS T. DRIVAS
JEFFREY J. OELKE
ADAM GAHTAN
WHITE & CASE LLP
Attorneys for Defendant-Appellee
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200

FEBRUARY 22, 2005

Counsel Press, LLC (202) 783-7288 * (888) 277-3259

CERTIFICATE OF INTEREST

Counsel for appellee Pfizer Inc. certifies the following:

1. The full name of every party or amicus curiae represented by me is:

Pfizer Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Pfizer Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

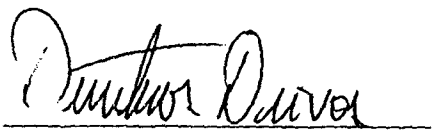
None

4. The names of all law firms and the partners or associates for the party or amicus curiae now represented by me in the trial court or agency or are expected to appear in this court are:

Dimitrios T. Drivas
Jeffrey J. Oelke
Adam Gahtan
Brendan G. Woodard
WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200

Timothy C. Blank
Matthew A. Porter
DECHERT LLP
Ten Post Office Square
Boston, Massachusetts 02109
Telephone: (617) 728-7100

Dated: February 22, 2005
New York, New York



Dimitrios T. Drivas
WHITE & CASE LLP

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ARGUMENT

Rehearing and rehearing *en banc* are appropriate only "to secure or maintain uniformity of the court's decisions" or "if the proceeding involves a question of exceptional importance." Fed. R. App. P. 35(a). In affirming that the District Court did not have subject matter jurisdiction over Teva Pharmaceuticals U.S.A., Inc.'s ("Teva") declaratory judgment action against Pfizer Inc. ("Pfizer"), the majority applied the same two-part test for declaratory jurisdiction that this Court and its predecessor Court have applied for decades, leaving the uniformity of this Court's cases intact. Teva Pharm. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, 1337 (Fed. Cir. 2005). Moreover, Congress recently mandated continued application of the test for declaratory judgment actions under Hatch-Waxman, rejecting automatic jurisdiction or alternative tests. Accordingly, there is no exceptionally important question for this Court to address, and rehearing is inappropriate.

I. REHEARING IS INAPPROPRIATE BECAUSE TEVA HAS IDENTIFIED NO DECISION OF THIS COURT THAT IS IN CONFLICT WITH THE PANEL'S DECISION

Teva's counsel asserts that the panel decision in this appeal is contrary to four earlier panel decisions of this Court: Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466 (Fed. Cir. 1997); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997); Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322 (Fed. Cir. 2003);

Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731 (Fed. Cir. 1988). Nothing about these cases is contrary to the panel's decision.

Three of these cases do not even concern subject matter jurisdiction in actions for declarations of patent non-infringement or invalidity. In Glaxo, patentee was the plaintiff, and the Court addressed only what a patentee must show for subject matter jurisdiction in a patent declaratory action. 110 F.3d at 1571. Not surprisingly, the Court applied a version of the same reasonable apprehension test that the panel applied in this case. Id. The patentee was also plaintiff in Allergan, in which the Court did not address declaratory judgment jurisdiction at all, but rather decided whether a patentee may bring an action under 35 U.S.C. § 271(e)(2) for inducement of infringement. 342 F.3d 1330-32. In Fina Oil – an inventorship case in which, again, patentee was plaintiff – the Court noted that there was no one test for jurisdiction in a patent declaratory action, but then applied a version of the reasonable apprehension test. 123 F.3d at 1470-71. Teva nowhere explains how these cases conflict with the majority's routine application of that test.

Teva does attempt to show that Arrowhead conflicts with the majority's decision on the question of whether reasonable apprehension must be of "imminent" suit. (Teva Pet. at 14.) In Arrowhead, the Court ruled only that imminence of suit was not required "when defendant is exhibiting an intent to

delay . . . suit until after defendant's extra-judicial enforcement efforts have failed and a trial date more convenient for defendant has arrived." 846 F.2d at 736. The Court had earlier determined that patentee had been terrorizing plaintiff with direct and indirect threats of suit. Id. at 734-35. In this case, in critical contrast, the majority correctly determined that Pfizer had done nothing to create any apprehension of suit on Teva's part. Teva Pharm. USA, 395 F.3d at 1334. The "imminence" requirement is discussed further in Section II, below.

II. BECAUSE THE MAJORITY APPLIED THIS COURT'S LONG-STANDING ANALYSIS, REHEARING IS INAPPROPRIATE

According to Teva, the majority gave the reasonable apprehension test a constitutional significance that it never had before, creating a divergence in the cases that only an *en banc* decision can resolve. (Teva Pet. at 12-14.) In fact, the majority decision was in complete harmony with the law of this Court and its predecessor, there is no conflict for this Court to resolve on rehearing, and no reason for this Court to disown a test that it has applied for decades.

The two-part test, including the reasonable apprehension analysis, predates the existence of this Court. See, e.g., Int'l Harvester Co. v. Deere & Co., 623 F.2d 1207, 1210 (7th Cir. 1980); Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc., 439 F.2d 871, 874-75 (1st Cir. 1971); Wembley, Inc. v. Superba Cravats, Inc., 315 F.2d 87, 89-91 (2d Cir. 1963). This Court adopted the test, and has applied it consistently. BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir.

1993); see also, e.g., Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999); Lang v. Pacific Marine & Supply Co., 895 F.2d 761, 764 (Fed. Cir. 1990); Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985); Jervis B. Webb Co. v. S. Sys., Inc., 742 F.2d 1388, 1398-99 (Fed. Cir. 1984).

As the majority explained, the test has always served the constitutional function of determining the existence of a justiciable controversy under Article III. Teva Pharm. USA, 395 F.3d at 1335-36. This Court recently elaborated:

> For a district court to have jurisdiction over a declaratory judgment action, there must be an "actual controversy." 28 U.S.C. § 2201(a). This requirement is identical to the constitutional requirement of Article III that there be a case or controversy. *See, e.g., Aetna,* 300 U.S. at 239-40, 57 S.Ct. 461. When a declaratory judgment plaintiff alleges that the claims of a patent are not infringed, invalid, or unenforceable, we apply a two-step test to determine whether there is an actual controversy. This two-step inquiry provides that there must be '(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.'

Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1326 (Fed. Cir. 1998) (citation omitted, emphasis in original), overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356 (Fed. Cir. 1999). This Court has reaffirmed the constitutional nature of the two-part test even more

recently. See, e.g., Capo, Inc. v. Dioptics Med. Prods., Inc., 387 F.3d 1352, 1355 (Fed. Cir. 2004); Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1372-73 (Fed. Cir. 2004) ("Article III limits federal jurisdiction to suits that address a 'real and substantial controversy . .' . . . We have developed a two-part test to guide the case-or-controversy analysis in patent-based declaratory judgment suits. . .") (emphasis added) (citations omitted).

Notwithstanding this Court's clear explanations of the constitutional function of the reasonable apprehension test, Teva repeatedly complains that the majority improperly grounded the test in the Constitution.[1] For example, Teva points out that the "'reasonable apprehension' test is not mandated by Article III" (Teva Pet. at 12), as if the absence of the words "reasonable apprehension" from the Constitution renders the test merely prudential. The majority correctly rejected this argument as contrary to this Court's decisions. Teva Pharm. USA, 395 F.3d at 1335.

Teva also argues that the majority diverged from this Court's cases by requiring that Teva establish reasonable apprehension of "imminent" suit. (Teva Pet. at 15.) The "imminence" requirement is nothing new in evaluating declaratory jurisdiction, as the majority explained with reference to Supreme Court precedent. Teva Pharm. USA, 395 F.3d at 1333. Unless apprehension had to be of

[1] Amici raise the same issue. (FTC Br. at 6-7; GPhA Br. at 6-7.)

"imminent" suit, moreover, it would take nothing more than knowledge of a competitor's patent – for example through marking on a product – to establish jurisdiction. "More is needed than knowledge or notice of an adversely held patent" to establish an actual controversy, however. Capo, 387 F.3d at 1355. The reasonable apprehension analysis "focuses on whether the patentee manifested the intention to enforce the patent." Id. Accordingly, in Arrowhead, which Teva cites as in conflict with the majority's decision, the Court held that a showing of imminence was not necessary because patentee had already effectively threatened to sue. 846 F.2d at 736. In this case, in contrast, the majority correctly held that Pfizer had done nothing to suggest imminent or even eventual suit, and Teva has not renewed its argument that it had reasonable apprehension. Teva Pharm. USA, 395 F.3d at 1344.

Because the majority followed a long-established line of this Court's cases, there is no disruption in uniformity and no basis for rehearing.

III. THIS COURT MAY NOT CREATE AUTOMATIC JURISDICTION FOR ANDA-FILERS IN HATCH-WAXMAN CASES

Teva and amici in support of rehearing want this Court to establish automatic jurisdiction for ANDA-filers in declaratory actions brought under Hatch-Waxman. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (the "Medicare Amendments"), Congress expressly rejected automatic jurisdiction in favor of the traditional reasonable

apprehension test, and this Court must apply the statute as enacted and according to clear Congressional intent.

A. Congress Has Expressly Rejected Automatic Jurisdiction

Teva argues that the recent Medicare Amendments, which direct courts in ANDA cases to exercise declaratory jurisdiction "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5), "restrict[s] the application of the 'reasonable apprehension' test to those instances where Article III required it." (Teva Pet. at 6.) Teva gives no example of an instance in which the test would still apply, however, and in effect asks this Court to interpret the Amendments as creating declaratory jurisdiction every time a patentee fails to sue the ANDA-filer for patent infringement within 45 days of receiving the ANDA-filer's paragraph IV notice. (Teva Pet. at 6-8.)[2]

According to Teva, automatic jurisdiction is necessary to serve the Medicare Amendments' underlying goals. (Teva Pet. at 8.) The legislative history of the Medicare Amendments directly addresses declaratory jurisdiction. Recapped in the majority decision, Teva Pharm. USA, 395 F.3d at 1336-37, and briefly here, the legislative history conveys Congress's rejection of automatic jurisdiction and its expectation that courts will continue to apply the reasonable apprehension test in ANDA cases.

An earlier version of the amendments would have created automatic jurisdiction along the lines of Teva's proposal. (See, Teva Pharm. USA, 395 F.3d at 1336.) That version did not become law, however, because of concerns about the constitutionality of legislating the existence of "subject matter jurisdiction . . . based on the failure to bring a suit . . . particularly in light of [the] manner in which the U.S. Courts of Appeals, including the Federal Circuit, have developed and applied the 'reasonable apprehension' test." 149 Cong. Rec. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch); see also 149 Cong. Rec. S16,104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch) (describing automatic jurisdiction as a "constitutional flaw"). Consequently, the bill that became new 35 U.S.C. § 271(e)(5) did not contain the automatic jurisdiction language of the earlier bill. In prescient contradiction to Teva's position today, the Conference Committee Report on the final bill explains:

> 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. The conferees expect the courts to examine as part of their analysis the particular policies

[2] Amici likewise assert that the Medicare Amendments broadened declaratory jurisdiction in Hatch-Waxman cases. (FTC Br. at 8 n. 5; GPhA Br. at 6.)

> 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. 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) (citations omitted) (emphases added). Senator Hatch, co-sponsor of the original Hatch-Waxman Act, emphasized that the Conferees intended to retain the reasonable apprehension requirement after enactment of the Medicare Amendments:

> In any event, in the provision the Senate considers today, the settled case law of the "reasonable apprehension" test remains undisturbed and the Constitutional requirements are observed. In adopting this language it is important to note that the presence of the two factors referred to in the statute, the filing of an ANDA application with a Paragraph IV patent challenge certification and the absence of a suit filed by the patent-holding innovator firm, do not alone satisfy the reasonable apprehension test. Certainly courts should, and in fact, must under the new language consider these two important factors but that should neither be the start nor the end of the inquiry. . . . I also want to make explicit, the implicit – that nothing in this new language pertaining to pharmaceutical patent-related declaratory judgments creates a new cause of action separate from the existing authority under title 28.

149 Cong. Rec. S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch) (emphases added).

By applying the reasonable apprehension test, therefore, the majority acted exactly according to Congressional instruction and in keeping with this Court's jurisprudence. Teva's arguments that the "panel's holding makes the decision to enact the amendment utterly inexplicable," and that automatic jurisdiction is more consistent than reasonable apprehension with the goals of Hatch-Waxman (Teva Pet. at 7), are wrong and beside the point. Even *en banc*, this Court must apply the statute as written in a manner that is consistent with Congressional intent, regardless of its view of what might better serve certain policy objectives or better explain Congress's decision to create new section 271(e)(5). Reid v. Dep't of Commerce, 793 F.2d 277, 284 (Fed. Cir. 1986) ("'Congress may amend the statute; we may not.'") (quoting Griffith v. Oceanic Contractors, Inc., 458 U.S. 564, 576 (1982)).

B. Orange Book Listing Cannot Create Reasonable Apprehension

In his dissent, Judge Mayer adopted Teva's argument that the act of listing a patent in the Orange Book creates reasonable apprehension in every case, for every ANDA-filer, Teva Pharm. USA, 395 F.3d at 1341, a rule that would effectively result in impermissible automatic jurisdiction. The majority correctly dismissed the argument, reasoning that by submitting information for listing in the Orange Book, Pfizer was complying with a statutory requirement, not making a "blanket threat to potential infringers." Teva Pharm. USA, 395 F.3d at 1333. This

conclusion is consistent with Congress's determination that "a court may or may not find a reasonable apprehension of suit" where there has been a paragraph IV certification on an Orange Book patent. H.R. CONF. REP. NO. 108-391, at 836 (2003).

In addition to the constitutional and legislative prohibitions on automatic jurisdiction, Judge Mayer's proposed rule is not practical in view of the statute's requirements. A party filing a New Drug Application ("NDA") is required to supply information for "any patent" that meets the statute's criteria, including patents that it does not own or control. 21 U.S.C. § 355(b)(1); Aaipharma Inc. v. Thompson, 296 F.3d 227, 236 (4th Cir. 2002); Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1079 (D.C. Cir. 2001). That information is then published in the Orange Book. 21 U.S.C. § 355(j)(7)(A). Under Judge Mayer's approach, an NDA applicant automatically creates reasonable apprehension, and so jurisdiction, with respect to every patent that it submits for listing, including those that it cannot enforce. This is an obviously incorrect result.[3]

[3] In its petition, Teva takes a new approach to the effect of Orange Book listing on jurisdiction, alleging that "Congress has determined that a generic company's uncertainty concerning the application of an Orange Book patent is in itself an injury that warrants legal remediation." (Teva Pet. at 12.) Teva cites no authority for this proposition, which, as discussed above, is contrary to Congress's recent pronouncement that a paragraph IV challenge on an Orange Book patent, coupled with the absence of a lawsuit by the patentee, will not necessarily result in declaratory jurisdiction.

IV. TEVA'S POLICY-BASED ARGUMENTS FOR APPLYING A DIFFERENT TEST ARE NOT GROUNDS FOR REHEARING

Teva and the amici argue that jurisdiction is appropriate, without regard to the reasonable apprehension test, because Teva has suffered an injury traceable to Pfizer's conduct and redressible by a declaratory judgment. (Teva Pet. at 10-12, 15; FTC Br. at 7-9; GPhA Br. at 8-9.) Teva's "injury" is that, without a declaration of invalidity or non-infringement of Pfizer's '699 patent, Teva's rival Ivax will enjoy a 180-day period of market exclusivity upon expiration of the earlier-to-expire '518 patent, "delaying" Teva's launch and possibly requiring Teva to launch at risk of liability, results that, Teva argues, are contrary to the purposes of Hatch-Waxman. (Teva Pet. at 10-12, 15; FTC Br. at 7-9; GPhA Br. at 8-9.) By listing the '699 patent in the Orange Book and not suing Teva for infringement, Pfizer is apparently responsible for Teva's injury. (Teva Pet. at 10-12; FTC Br. at 7-9; GPhA Br. at 8-9.)

Teva and amici insist that this alternative "injury" test is appropriate in ANDA cases because the regulatory scheme of Hatch-Waxman does not accommodate the traditional reasonable apprehension test. (FTC Br. at 7.) In addition, they argue, as this Court has never restricted the jurisdictional analysis to the reasonable apprehension test, the majority improperly felt itself bound to apply it. (Teva Pet. at 9.) The short and complete answer to this argument, of course, is that Congress has recently required continued application of the

reasonable apprehension test to determine jurisdiction in ANDA cases. (See, Section II, above.) A departure from the test would therefore both disrupt this Court's jurisprudence and contradict Congressional intent.

In any event, the argument does not withstand constitutional scrutiny. In effect, Teva and the amici want this Court to recognize the existence of declaratory judgment jurisdiction in ANDA cases "as an avenue by which" generics can "obtain FDA approval" and deprive the primary ANDA-filer of its Congressionally mandated exclusivity period, not because there is an actual patent dispute between the parties to the litigation. (E.g., FTC Br. at 8; GPhA Br. at 4-6, 8-9.) The majority rejected this argument because it appreciated this disconnect between Teva's "injuries" and any real patent dispute, the existence of which must be the focus of the jurisdictional analysis in a patent declaratory action:

> 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.... 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.

Teva Pharm. USA, 395 F.3d at 1338. The majority correctly concluded that a patent declaratory case against Pfizer was an inappropriate medium for addressing

Teva's concerns, and directed Teva to the legislature, which created the 180-day exclusivity, as a more appropriate forum. Id.

The majority's reasoning is consistent with Congress's instruction that the Medicare Amendments did not create "a new cause of action separate from the existing authority under" the Declaratory Judgment Act. (149 Cong. Rec. S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch).) Moreover, Congress instituted exclusivity forfeiture, not guaranteed litigation, as the relief for secondary ANDA-filers whose approvals are genuinely delayed, Medicare Amendments, § 1102(a)(2), 117 Stat. 2066, 2458-60 (2003) (codified as amended at 21 U.S.C. § 355(j)(5)(D)), further discrediting the argument that Congress intended to expand declaratory jurisdiction beyond actual patent disputes to cases brought for the purpose of expediting ANDA review.

Because Congress has clearly endorsed this Court's own approach to determining the existence of declaratory jurisdiction, rehearing is unnecessary.

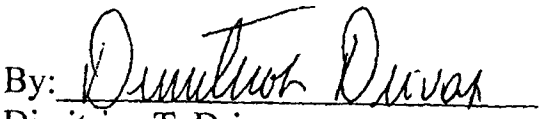
CONCLUSION

For the foregoing reasons, this Court should deny Teva's petition for a panel rehearing or rehearing *en banc*.

Respectfully submitted,

Dated: February 22, 2005

WHITE & CASE LLP

By: 

Dimitrios T. Drivas
Jeffrey J. Oelke
Adam Gahtan
1155 Avenue of the Americas
New York, New York 10036
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Attorneys for Defendant-Appellee Pfizer Inc.

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 22nd day of February, 2005, I filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, via hand delivery, the 15 number of copies of this OPPOSITION OF DEFENDANT-APPELLEE TO COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC, and further certify that I served 2 copies of said Brief to the following:

1. HENRY C. DINGER (via Federal Express)
   GOODWIN PROCTER LLP
   Exchange Place
   53 State Street
   Boston, Massachusetts 02109
   (617) 570-1000

2. WILLIAM L. MENTLIK (via Federal Express)
   LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP
   600 South Avenue West, Ste. 300
   Westfield, NJ 07090-1497
   (908) 654-5000
   Counsel for Amicus Ivax Pharmaceuticals, Inc.

3. ROBERT J. MULDOON, JR. (via Federal Express)
   SHERIN AND LODGEN LLP
   100 Summer Street
   Boston, Massachusetts 02110
   Counsel for Appellant

4. SARAH LENZ LOCK (via Federal Express)
   AARP Foundation
   601 E Street, NW,
   Washington, DC 20049
   (202) 434-2060
   Counsel for Amicus AARP

5. LAWRENCE DEMILLE-WAGMAN (via Federal Express)
FTC
600 Pennsylvania Ave., N.W., Room H-582
Washington, DC 20580
(202) 326-2448
Counsel for Amicus FTC

6. BRIAN T. MORIARTY (via Federal Express)
SONNENSCHEIN NATH & ROSENTHAL LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 768-6700
Counsel for Amicus Generic Pharmaceutical Association

February 22, 2005

John C. Kruesi, Jr.
Counsel Press, LLC