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 Case No. 03-CV-10167, Judge Richard G. Stearns

BRIEF OF *AMICUS CURIAE* IVAX PHARMACEUTICALS, INC. SUPPORTING APPELLEE IN OPPOSITION TO PETITION FOR REHEARING AND FOR REHEARING *EN BANC*

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February 18, 2005

CERTIFICATE OF INTEREST

Counsel for *amicus curiae*, IVAX PHARMACEUTICALS, INC. certifies the following:

1. The full names of every party or amicus represented by me are:

IVAX Pharmaceuticals, Inc.

2. The names of the real parties in interest represented by me are:

None.

3. The parent companies, subsidiaries (except wholly owned subsidiaries) and affiliates that have issued shares to the public of the party, or amicus curiae, represented by me are:

IVAX Corp.

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

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I. STATEMENT OF IDENTITY AND INTEREST OF THE *AMICUS CURIAE*

Amicus curiae IVAX Pharmaceuticals, Inc. ("IVAX") develops and markets low-cost generic drug products through the filing of Abbreviated New Drug Applications ("ANDAs"). As recognized by the district court (A4, A7-8 n.8) and by the panel (slip op. at 8-9), IVAX was the first to file an ANDA in connection with ZOLOFT®, which included a paragraph IV certification challenging Pfizer's '699 patent. As a result of that early and substantial commitment of resources, IVAX is eligible for a 180-day period of market exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv). Plaintiff-appellant Teva Pharmaceuticals USA, Inc. ("Teva") initiated its declaratory judgment action with the avowed objective of causing IVAX's potential right to exclusivity to begin and expire before IVAX could enjoy it. Thus, IVAX wishes to present its views to this Court as to why Teva should not be permitted to gratuitously destroy IVAX's exclusivity under the unique circumstances of this case.

II. ARGUMENT

In its petition for rehearing and for rehearing *en banc*, Teva states:

> Congress opted for a measure that *directed federal courts to exercise jurisdiction* to the constitutional limit, but left for the courts the definition of those limits.

(Pet. at 7 (emphasis added).) Teva has further argued that "Congress has *directed the exercise of jurisdiction* 'to the extent consistent with the Constitution' . . . ." (*Id.* at 9 (emphasis added).) Lest the import of that argument be misunderstood, Teva specifically asserted in its principal brief:

> Moreover, even though the Declaratory Judgment Act in general permits courts to exercise discretion not to hear cases, despite the existence of an actual controversy, . . . *the congressional mandate to entertain such suits to the constitutional limit has eliminated such discretion in cases brought by ANDA applicants to declare a listed patent invalid or not infringed.*

(Teva Blue Br. at 57 n.1 (emphasis added); *see also* Apotex Br. at 4 ("federal courts *must* exercise jurisdiction . . . (emphasis added).)

Teva thus suggests that, in the 2003 Medicare Amendments, Congress not only "directed" the courts to find *jurisdiction* to the full extent permitted by the Constitution, but also stripped the district courts of their long-standing *discretion* to decline declaratory jurisdiction.

IVAX takes no position on the question of jurisdiction. However, Teva's contention that the 2003 Medicare Amendments stripped courts of discretion to decline to hear cases in which jurisdiction exists is wrong. Moreover, discretion can and should be exercised here to decline jurisdiction because (i) Teva's avowed purpose in initiating litigation was to trigger IVAX's exclusivity at a time when IVAX would not be able to enjoy it, and (ii) Teva has made no attempt to

bring a generic version of ZOLOFT® to the public any earlier than was assured by IVAX's settlement with Pfizer.

A. The Medicare Amendments Did Not Strip Courts Of Discretion To Decline To Entertain Declaratory Actions

1. The Word "May" In § 2201 Is The Statutory Source Of Discretion In Declaratory Judgment Actions

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), states:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, *may* declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

Id. (emphasis added).

The existence of discretion, and the source of that discretion being the use of the word "may" in § 2201, has repeatedly been recognized by this Court in the context of patent litigation. For example, in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988), this Court stated:

> There is no absolute right to a declaratory judgment. The Act says a court "may" grant one. Hence, when there is a clear controversy and thus jurisdiction, a district court's decision on whether to exercise that jurisdiction is discretionary.

Id. at 735 n.6. *See also Serco Servs. Co. v. Kelley Co.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995); *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 936 (Fed. Cir. 1993). Any doubt that the use of "may" in § 2201 vested courts with discretion was erased in *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995):

> Since its inception, the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants. On its face, the statute provides that a court "*may* declare the rights and other legal relations of any interested party seeking such declaration," 28 U.S.C. § 2201(a) (1988 ed., Supp. V) (emphasis added).
>
> . . . .
>
> We agree . . . that "there is . . . nothing automatic or obligatory about the assumption of 'jurisdiction' by a federal court" to hear a declaratory judgment action. Borchard, Declaratory Judgments, at 313. By the Declaratory Judgment Act, Congress sought to place a remedial arrow in the district court's quiver; it created an opportunity, rather than a duty, to grant a new form of relief to qualifying litigants.

Id. at 286-88.

Subsequent to *Wilton*, and in direct reliance thereon, this Court has reaffirmed — in the specific context of patent litigation — that the use of the word "may" in § 2201 vests courts with unique and substantial discretion. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813 (Fed. Cir. 1996).

2. By Specifically And Repeatedly Referencing § 2201, The Medicare Amendments Retained The Discretion Of Courts To Decline Declaratory Judgment Jurisdiction

Teva is wrong in asserting that courts no longer may decline declaratory jurisdiction in Hatch-Waxman cases. The repeated references in the 2003 Medicare Amendments to § 2201, which uses "may," makes clear that discretion remains. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I), (II); 35 U.S.C. § 271(e)(5).

In asserting that the Medicare Amendments ended all judicial discretion in Hatch-Waxman declaratory judgment actions, Teva relies heavily on the words of new 35 U.S.C. § 271(e)(5), to wit, "to the extent consistent with the Constitution . . . ." (Pet. at 5, 6.) But the statute clearly says that courts "shall . . . have subject matter jurisdiction" to the extent consistent with the Constitution. Thus, Congress was at most directing that the requirement of a controversy for *jurisdictional* purposes be expanded to its broadest and most liberal scope consistent with the Constitution. But this has nothing to do with the long-standing *discretion* embraced in 28 U.S.C. § 2201. The existence of jurisdiction and the question of discretion are distinct issues, with discretion typically addressed only *after* a court has concluded that it has jurisdiction.

B. Discretion May Be Exercised To Decline Jurisdiction In A Case Like This One

1. Teva's Motive To Destroy IVAX's Exclusivity Provides A Legitimate Basis To Exercise Discretion And Decline Jurisdiction

Using a declaratory judgment action as a "tactical measure" to "improve [the plaintiff's] posture" is a basis on which declaratory judgment jurisdiction may be declined. *EMC*, 89 F.3d at 815. Teva's filing of its declaratory judgment action for the avowed purpose of triggering IVAX's exclusivity so that it would begin and end before IVAX or Teva (or anyone else) could offer a

generic version of ZOLOFT® (*see, e.g.*, A149-50, 402, 493-94, 500-01, 503-05), *i.e.*, "to rob Ivax of its first filer status" (A8 n.7), was and is a legitimate factor to consider in exercising discretion as to whether to entertain Teva's action.

Teva itself has argued that the purpose of the 180-day period of exclusivity is to encourage generic drug companies to undertake the expense of challenging the validity of listed patents and/or inventing around them. (Teva Blue Br. at 20; *see also id.* at 40.) IVAX agrees. It was the prospect of 180 days of exclusivity that prompted IVAX to challenge Pfizer's '699 patent — a challenge that achieved much of IVAX's objective through a settlement that assures that IVAX can launch its product immediately after the '518 patent expires, some four years before the '699 patent expires.

IVAX vigorously contested Pfizer's patents. Contrary to Teva's assertion that IVAX and Pfizer "quickly settled" their case (A138), IVAX litigated with Pfizer for some 28 months, spending over $1.6 million on the litigation alone. Had Pfizer prevailed in all respects, IVAX could not have introduced its generic sertraline product until 2010. Instead, by the time Teva filed its complaint on January 24, 2003 (A11), IVAX's efforts had already assured that a generic ZOLOFT® would become available no later than 2006.

IVAX acknowledges the statement in *Minnesota Mining & Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 781 (Fed. Cir. 2002) ("*3M*"), that a second or subsequent ANDA filer does not have an obligation to avoid triggering the 180-day exclusivity period of the first filer. However, nothing in *3M* suggests that the district court, in exercising discretion under 28 U.S.C. § 2201, could not (i) take into account the fact that Teva's primary motivation in commencing its action was to trigger the running of IVAX's exclusivity before it could get a product on the market, and (ii) consider whether allowing Teva to proceed would run counter to the policy of encouraging generic drug companies to be the first to challenge a patent.

2. Teva's Failure To Seek FDA Approval Before IVAX Enters The Market Provides A Further Basis For The Court To Exercise Discretion And Decline Jurisdiction

Teva's briefs may create the illusion that Teva has taken steps which could result in a generic substitute for ZOLOFT® getting to consumers *earlier* than contemplated by the Pfizer-IVAX settlement. But that is simply not the case. Teva filed a *paragraph III* certification as to Pfizer's '518 patent — just as IVAX had.

Thus, nothing that Teva did in this case could have brought a generic version of ZOLOFT® to the public any earlier than the 2006 date contemplated

by the Pfizer-IVAX settlement. Teva's motivation was simply to get a piece of the action — at IVAX's expense — when generic competition begins in 2006 (which presupposes that Teva would win its case, absent which it would be barred from competing until 2010).

The equities might be different here if Teva had challenged the '518 patent. Had it done so expeditiously, it is possible that generic ZOLOFT® might have come to market *before* 2006. To be sure, nothing in the Pfizer-IVAX settlement papers (A337-95) would have prevented that from occurring.

This is not a case where a second or subsequent filer of an ANDA has taken actions which might *advance* the beginning of generic availability. Here, the later filer Teva has done *nothing* to bring about generic availability any earlier than the date achieved through the efforts of the first filer, and seeks only to strip IVAX of its exclusivity. These are facts which the district court and/or this Court can and should take into account in exercising discretion *not* to entertain Teva's declaratory judgment action.

3. This Case Involves No "Bottleneck," "Roadblock," Or "Parking" Of Exclusivity

Teva's *amicus*, the Generic Pharmaceutical Association (GPhA"), complains about the problem of "parking" exclusivity. (*See* GPhA Br. at 5.) But there is no evidence on this record that IVAX intends to wait even a single day

before it introduces its generic sertraline product upon expiration of Pfizer's '518 patent and pediatric exclusivity in 2006. Given that no generic competitor (including Teva) has seen fit to challenge Pfizer's '518 patent, IVAX's planned launch thus will take place at the earliest possible moment.

4. No Statute Or Policy Mandates "Full Generic Competition" At The Very Outset

The GPhA argues that Hatch-Waxman's purpose is "to permit all eligible generics to get on the market as quickly as possible" (GPhA Br. at 4), what Teva previously called "full generic competition" (A134; Teva Blue Br. at 19). Intra-generic competition indisputably drives down prices. But Congress, which sought to promote *early* generic availability, consciously chose a scheme whereby *only* one generic would be available for the first 180 days and "full generic competition" could occur thereafter, and Congress retained that exclusivity mechanism when it amended the Hatch-Waxman Act in 2003. In this case, IVAX responded to this statutory incentive and achieved the objective of assuring the earliest possible generic availability.

Thus, exercising discretion to decline jurisdiction here would be consistent with the statutory policy of encouraging the *early* filing of ANDAs seeking to assure generic availability at the *earliest* possible time.

III. CONCLUSION

For the reasons set forth above, if this Court rehears this appeal and concludes that subject matter jurisdiction over Teva's action existed, this Court should make clear that the district court retains discretion to decline jurisdiction, and that this case involves circumstances where such an exercise of discretion would be appropriate.

Respectfully submitted,

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Dated: February 18, 2005

By: _____
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, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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I served the within Brief of *Amicus Curiae* Ivax Pharmaceuticals, Inc. Supporting Appellee in Opposition to Petition for Rehearing and for Rehearing *En Banc* in the above captioned matter upon:

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via **Express Mail** by depositing **2** copies of same, enclosed in a post-paid, properly addressed wrapper, in an official depository maintained by United States Postal Service.

Unless otherwise noted, copies have been sent to the court on the same date as above for filing via Federal Circuit.

Sworn to before me on February 18, 2005

MICHAEL DESANTIS
Notary Public, State of New York
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