Appeal No. 06-1181

United States Court of Appeals

for the

Federal Circuit

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

– v. –

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY IN CASE NO. 05-CV-2881, JUDGE JOSE L. LINARES

BRIEF FOR DEFENDANTS-APPELLEES

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MAY 12, 2006

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Teva Pharmaceuticals USA Inc. v. Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd.

No. 06-1181

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Novartis Pharmaceuticals Corp. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:
Novartis Pharmaceuticals Corporation, Novartis Pharma AG, and Novartis International Pharmaceutical Ltd.

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:
None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:
Novartis AG is the parent company of Novartis Pharmaceuticals Corporation. Novartis AG is the only publicly held company that directly or indirectly owns 10% or more of Novartis Pharmaceuticals Corporation stock.
Novartis AG is the parent company of Novartis Pharma AG. Novartis AG is the only publicly held company that directly or indirectly owns 10% or more of Novartis Pharma AG stock.
Novartis AG is the parent company of Novartis International Pharmaceutical Ltd. Novartis AG is the only publicly held company that directly or indirectly owns 10% or more of Novartis International Pharmaceutical Ltd. stock.

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

5. 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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STATEMENT OF RELATED CASES

No other appeal in or from the same civil action in the district court was previously before this or another appellate court. The Court's decision in this case may affect Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc., No. 05-1887 (D.N.J. filed April 8, 2005), a case involving the same drug as the present declaratory judgment action, but a different patent.

STATEMENT OF JURISDICTION

1. The district court lacked subject matter jurisdiction because there is no real and present controversy as required by 28 U.S.C. §§ 2201 and 2202.

2. This Court has jurisdiction for the appeal under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

1. Whether the Hatch-Waxman Act provides for automatic declaratory judgment jurisdiction for all non-asserted Orange Book patents.

2. Whether, under the totality of the circumstances, the fact that Novartis sued Teva on one Orange Book patent for Famvir® automatically gives rise to reasonable apprehension on Teva's part sufficient to support declaratory judgment jurisdiction on the remaining Orange Book patents.

3. Whether, under the totality of the circumstances, the fact that Novartis sued Teva on one Orange Book patent gives rise to reasonable apprehension on Teva's part sufficient to support declaratory judgment jurisdiction on the remaining Orange Book patents, where (a) the patent sued on and the remaining patents are not "identical" and do not cover the same inventions, and (b) Novartis considered Teva's allegations against all of the patents for 45 days and then elected to sue on one but not the remaining patents.

STATEMENT OF THE FACTS AND OF THE CASE

A. Novartis Markets Famciclovir Under The Tradename Famvir®

Famciclovir was developed in the U.K. in the mid-1980's by scientists working for The Beecham Group, who subsequently demonstrated in clinical trials that famciclovir was effective for the treatment of infections, particularly herpes zoster. In 1989, The Beecham Group merged with SmithKline Beckman to form SmithKline Beecham ("SmithKline"). SmithKline filed its famciclovir New Drug Application ("NDA") in June, 1993 and it received the approval of the Food & Drug Administration ("F.D.A.") in June, 1994. SmithKline commenced its marketing of famciclovir tablets in the United States in 1994 under the tradename Famvir®.

In 2001, after the merger of SmithKline and Glaxo Wellcome, the Famvir® business, including the intellectual property, was sold to Novartis. Since that time, Novartis has been the exclusive marketer of Famvir® tablets in the United States. Sales of Famvir® in the United States amounted to more than $150 million in the year 2005.

B. <u>The Famvir® Patents</u>

Five patents are listed under the Famvir® entry in the F.D.A.'s Orange Book. Included is the basic famciclovir patent -- U.S. Patent No. 5,246,937 ("the '937 patent") -- with claims to famciclovir itself and to the method of using famciclovir to treat viral infections, including herpes. (A287–300). The remaining four patents cover additional methods of treatment. Two of these -- U.S. Patent Nos. 5,840,763 ("the '763 patent") and 5,916,893 ("the '893 patent") -- claim methods for treating, and reducing, "latent" herpes infections. (A19–22; A34–38). The remaining two patents -- U.S. Patent Nos. 5,866,581 ("the '581patent") and 6,124,304 ("the '304 patent") -- claim methods for treatment of two types of pain that are caused by herpes infections, i.e., zoster associated pain ("ZAP") and post-herpetic neuralgia ("PHN"). (A23–33; A39–48).

Teva refers to the four additional patents as the "Related Patents". A more appropriate expression is "the DJ patents" -- Novartis will use that expression throughout the rest of its brief.

1. The Basic '937 Famciclovir Patent

The '937 patent, entitled "Purine Derivatives", issued in September, 1993 and expires in September, 2010. (A287). The chain of patent applications resulting in the '937 patent was filed in the U.S. Patent and Trademark Office ("USPTO") between 1985 and 1992 in the names of Michael Harnden and Richard Jarvest -- two chemists working for The Beecham Group at the time of their invention. (A287).

The '937 patent teaches the discovery of a particular class of "purine" compounds -- including famciclovir -- that are useful in treating viral infections. The patent has claims to the class of purines (e.g., Claim 1), to famciclovir (e.g., first member of Markush group of Claim 6), to pharmaceutical compositions containing famciclovir (e.g., Claim 19), to a method of treating viral infections using famciclovir (e.g., Claim 14) and to a method of treating herpes infections using famciclovir (e.g., Claim 15). (A295–96). Novartis has already asserted the '937 patent against Teva. See Statement of Related Cases, supra.

2. The DJ Patents

The DJ patents cover additional methods of using famciclovir. They are not "identical" to the '937 patent.

a. The '763 And '893 "Latency" Patents

The '763 and '893 patents entitled, "Treatment Of A Latent Infection Of Herpes Viruses", issued in November, 1998 and June, 1999, respectively. Both patents expire in November, 2015. (A19; A34). The '763 and '893 patents issued from the same chain (or "family") of related patent applications. (A34). The applications were filed in the USPTO between 1995 and 1997 in the names of Hugh Field, Alana Thackray, Teresa Bacon, David Sutton and Richard Hodge, claiming priority from patent applications filed in the U.K. in 1994 and 1995. (A19; A34). The term of the '893 patent was terminally disclaimed past the expiration date of the related '763 patent. (A34). The chain of patent applications resulting in the '763 and '893 patents is not connected to the chain of patent applications resulting in the '937 patent. The '763 and '893 patents teach that famciclovir can be used to treat the latent infection of a herpes virus. (A19–23; A34–38). "Latency" results when the virus goes "underground" in the body, ceasing to generate symptoms, but can then reappear without warning.

The USPTO did not require that the ‘763 or ‘893 patents be terminally disclaimed against the ‘937 patent, thus confirming that the claimed inventions are not only different, but are also patentably distinct.

b. The ‘581 And ‘304 Pain Patents

The ‘581 patent, entitled “Penciclovir For The Treatment Of Post Therapeutic Neuralgia”, issued in February, 1999 and expires in October, 2014. (A23). The ‘304 patent, entitled “Penciclovir For The Treatment Of Zoster Associated Pain”, issued in September, 2000 and also expires in October, 2014. (A39). The ‘581 and ‘304 patents issued from the same chain (or “family”) of related patent applications. (A23; A39). The applications were filed in the USPTO between 1994 and 1998 in the names of Ronald Boon and David Griffin, claiming priority from patent applications filed in the U.K. in 1993. (A23; A39). The term of the ‘304 patent was terminally disclaimed past the expiration date of the related ‘581 patent. (A23). The chain of patent applications resulting in the ‘581 and ‘304 patents is not connected to the chain of patent applications resulting in the ‘937 patent. The ‘581 patent teaches that famciclovir (as well as its metabolite penciclovir) is useful for reducing the duration of PHN, an intense neuropathic pain caused by herpes zoster. (A23–34). The ‘304 patent teaches that

famciclovir (as well as its metabolite penciclovir) is useful for reducing the duration of ZAP, a class of neuropathic pain caused by herpes zoster. (A39–48).

The USPTO did not require that the '581 or '304 patents be terminally disclaimed against the '937 patent, thus confirming that the claimed inventions of these patents, like the '763 and '893 patents, are not only different, but are also patentably distinct from the invention of the '937 patent.

C. Teva's Notice Letter

Sometime shortly after February 22, 2005, Novartis received Teva's Notice Letter stating that Teva had filed an Abbreviated New Drug Application ("ANDA") with Paragraph IV Certifications directed to all five famciclovir patents listed in the Orange Book. (A301–20). With respect to the four DJ patents, Teva argued that most of the claims of the DJ patents are invalid and that some claims are not infringed as well because they recite different dosages or different compounds than Teva's product. (A301–20).

D. Novartis Subsequently Sued Teva For Infringement Of The '937 Patent

After Novartis received Teva's statutory Notice Letter describing the substance of Teva's patent challenges, Novartis did what the Hatch-Waxman Act said it should do -- it reviewed the situation regarding both the challenged patents and Teva's proposed generic product, all with a view to deciding whether to bring

suit on one or more of the challenged patents within the 45 days allowed by the statute.

On April 8, 2005, and within the 45-day time period, Novartis brought suit against Teva in the District Court for the District of New Jersey for infringement of the basic '937 patent. (A321–28). That suit, identified in Novartis' Statement of Related Cases, supra, is currently pending before Judge Dennis M. Cavanaugh. Novartis did not sue Teva on any of the DJ patents.

As far as Novartis is aware, no company other than Teva has filed an ANDA for generic famciclovir. Moreover, Novartis has not filed suit against anyone else on any of the five listed famciclovir patents.

E. Teva Brought Its Own Declaratory Judgment Action In June, 2005

Teva brought its declaratory judgment action on June 3, 2005 in the District Court for the District of New Jersey challenging the validity and infringement of the DJ patents. (A49–62). Pertinent here is the fact that Teva brought its declaratory judgment action by a separate complaint rather than as a counterclaim in the '937 patent litigation -- a decision that is inconsistent with any belief that the subject matter of the DJ patents is the same as the '937 patent.

Teva's separate suit was ultimately assigned to Judge Jose Linares. Consistent with the conclusion that the DJ patents are not the same as the '937 patent, Teva never moved pursuant to the New Jersey Local Rules to have its declaratory judgment action reassigned to Judge Cavanaugh so that it could be consolidated with the '937 action.

Novartis filed its motion to dismiss Teva's separate complaint on August 15, 2005. (A63–95). The District Court granted Novartis' motion on December 12, 2005. (A1).

SUMMARY OF THE ARGUMENT

If this Court is to find jurisdiction for Teva's declaratory judgment action, Teva must demonstrate "reasonable apprehension" of imminent suit on the DJ patents. Many of the factors that Teva relies on in support of its reasonable apprehension in this case were likewise present in Teva's prior case against Pfizer on the drug Zoloft®, a case this Court dismissed for lack of reasonable apprehension. Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324 (Fed. Cir. 2005), reh'g en banc denied, 405 F.3d 990 (Fed. Cir. 2005), cert. denied, 126 S. Ct. 473 (2005). These factors include Novartis' listing of the patents in the Orange Book, Novartis' refusal to provide Teva a covenant not to sue, and the fact

that Novartis diligently protects its intellectual property. These factors do not carry the day for Teva in this case either.

Other factors that Teva relied upon in the Zoloft® case are not present here -- most notably the fact that Pfizer had sued another generic drug maker, Ivax, on the same patents that Teva subsequently included in its declaratory judgment action against Pfizer. In contrast, Novartis has never sued anyone for infringement of the DJ patents. Moreover, Teva has never suggested that Novartis has asserted its foreign counterparts of the DJ patents against Teva, or against anyone else. In fact, subsequent to the district court briefing period in this case, Novartis decided not to assert a Canadian counterpart patent to two of the DJ patents against Teva in Canada.

Teva then argues that the single, critical difference between this case and Teva v. Pfizer is the fact that Novartis has already brought suit against Teva on one of the Famvir® Orange Book patents. Teva had not been previously sued in the case of Teva v. Pfizer.

At most, the prior suit on the '937 patent is one factor to be assigned weight and then added up with the weights of the remaining factors to come up with a total "reading" on Teva's level of apprehension. In this case, Novartis carefully considered Teva's Paragraph IV Certifications in the 45-day time period

and then elected to sue Teva only on the '937 patent. This fact alone should eliminate any possible apprehension Teva might have had about being sued on the DJ patents. Indeed, if Novartis had sued on any of the DJ patents in the 45-day period, and was successful, the F.D.A. would be enjoined from approving Teva's ANDA until expiration of the DJ patents.

Moreover, the inventions of the asserted and non-asserted patents are simply not the same. The patent prosecutions were unrelated -- the inventors are different. The USPTO did not require that any of the DJ patents be terminally disclaimed against the '937 patent. Perhaps most pertinent -- and in contrast to the facts in Teva v. Pfizer -- Novartis has never asserted the DJ patents against anyone else. Under all of these circumstances, Teva cannot reasonably apprehend suit in the immediate future on the DJ patents.

Finally, to the extent Teva suggests in its brief that the "reasonable apprehension" test can simply be ignored in this case -- either because of Teva's interpretation of the Hatch-Waxman Act's "Civil Action To Obtain Patent Certainty", or because of Teva's interpretation of cases such as Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270 (1941), Teva is simply wrong. If the legislative history of the Hatch-Waxman Act clarifies anything, it is that the framers intended no shortcuts to declaratory judgment jurisdiction -- they argued

the issue up, down and sideways, ultimately concluding that an actual controversy under Article III of the Constitution was still required.

ARGUMENT

I. Standard Of Review

Dismissal of Teva's declaratory judgment action is a question of law reviewed by this Court de novo. Teva v. Pfizer, 395 F.3d at 1332. Underlying factual findings, however, may not be disturbed unless clearly erroneous. Gen-Probe, Inc. v. Vysis, Inc., 359 F.3d 1376, 1379 (Fed. Cir. 2004); see also Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 634 (Fed. Cir. 1991) (the appellate court "review[s] dismissal as a matter of law, keeping in mind that the District Court's view of the legal effect of the fact pattern before it is not to be lightly disregarded") (quotations and citations omitted); BP Chem. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993).

II. The Federal Circuit's "Reasonable Apprehension" Test Is Still The Law

A. Declaratory Judgment Jurisdiction Requires An Actual Controversy

The Declaratory Judgment Act requires an "actual controversy" between the parties to a litigation. 28 U.S.C. § 2201(a). Federal jurisdiction cannot exist in the absence of an actual case or controversy. If there is no actual controversy between the parties regarding the subject matter on which a

declaratory judgment is sought, the court must dismiss the action for lack of subject matter jurisdiction. Spectronics, 940 F.2d at 634 ("When there is no actual controversy, the court has no discretion to decide the case."); BP Chem., 4 F.3d at 977-78.

Teva, the declaratory judgment plaintiff, has the burden of demonstrating that there is an actual controversy. Spectronics, 940 F.2d at 634-35.

Even if there is an actual controversy, courts have "substantial discretion" to decline jurisdiction. Teva v. Pfizer, 395 F.3d at 1331. In its motion to dismiss before the district court, Novartis contended that even if the court concluded that an actual controversy existed, the court should still use its discretion to decline jurisdiction. (A85–89). The district court never reached the discretionary dismissal question, but instead dismissed based on lack of subject matter jurisdiction. (A12 at lines 15-17). If this Court finds that an actual controversy exists, it should remand to the district court to determine whether the district court should use its discretion to decline jurisdiction.

B. The Two-Prong Test For Actual Controversy

As the Federal Circuit explained with respect to patent rights, "for an actual controversy more is required than the existence of an adversely held patent." BP Chem., 4 F.3d at 978. To determine if there is an "actual controversy" in patent cases, the Federal Circuit created a two-prong test. Spectronics, 940 F.2d at 634. "First, the accused infringer must have actually produced or prepared to produce an allegedly infringing product." Id. The parties agree that this prong is satisfied by Teva's filing of its ANDA. Second, the party seeking jurisdiction must show that the patentee's conduct creates an objectively reasonable apprehension that the patentee will initiate imminent suit. Id.; see also Shell Oil Co. v. Amoco Corp., 970 F.2d 885, 888 (Fed. Cir. 1992). Any threat of suit that is purely subjective, prospective or of uncertain occurrence is insufficient. BP Chem., 4 F.3d at 979; Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 883 (Fed. Cir. 1985).

Whether Teva has a reasonable apprehension of suit is a factual question that requires the court to look to the totality of the circumstances. Gen-Probe, 350 F.3d at 1379-80. This is an objective test which focuses on whether the patentee's conduct rose to a level sufficient to indicate an intent to

enforce its patent through litigation. Shell, 970 F.2d at 887-88; BP Chem., 4 F.3d at 979.

It is well established law that the threat of suit cannot be remote. See, e.g., B.P. Chem., 4 F.3d at 977-78 (noting that the dispute must require an "immediate" determination of legal rights). In Teva v. Pfizer, this Court explained the importance of the immediacy requirement:

> In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of imminent suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Teva v. Pfizer, 395 F.3d at 1333.

Indeed, the Federal Circuit pointed out that because of the expiration date of the basic product patent, coupled with the first filer's (Ivax's) 180 days of marketing exclusivity, Teva had virtually conceded it could not be sued for a period of almost four years from the time it filed its declaratory judgment action. Id. at 1333-34.

III. Teva's Declaratory Judgment Action Lacks Subject Matter Jurisdiction

Teva's principal arguments in support of its reasonable apprehension here are taken practically verbatim from its arguments in Teva v. Pfizer -- Teva first cites to the Orange Book listing of the DJ patents, to Novartis' aggressiveness in protecting its intellectual property and to Novartis' refusal to give Teva a covenant not to sue. Teva even recycles its argument that the Hatch-Waxman Act's "Civil Action To Obtain Patent Certainty" provides automatic reasonable apprehension on non-asserted Orange Book patents. The only new argument Teva presents is the fact that Novartis previously sued Teva on the '937 patent.

Novartis shall demonstrate below that (1) the Hatch-Waxman Act has not abolished the reasonable apprehension test, (2) the Teva v. Pfizer factors Teva relies on here are less likely to result in reasonable apprehension under the circumstances of this case than they did in Teva v. Pfizer and (3) Novartis' suit against Teva on the '937 patent cannot raise Teva's apprehension of suit on the DJ patents to a reasonable level.

In short, Novartis will show that in this case Teva cannot have reasonable apprehension of imminent suit on the DJ patents.

A. The Hatch-Waxman Act Does Not Provide For Automatic Declaratory Judgment Jurisdiction

Teva first seeks a blanket ruling that, under the Hatch-Waxman Act, a generic drug maker will automatically have reasonable apprehension of suit as to any non-asserted Orange Book patents. Despite the Court's opinion in Teva v. Pfizer, 395 F.3d at 1334-38, Teva continues to point to the Hatch-Waxman Act's "Civil Action To Obtain Patent Certainty" at 21 U.S.C. § 355(j)(5)(C) as controlling in this situation. Suffice it to say that Congress carefully considered enacting a statute that granted automatic DJ jurisdiction on non-asserted patents, but then flatly rejected it.[1/]

In testimony before the U.S. Senate Committee on the Judiciary (August 1, 2003), Jon W. Dudas, Deputy Under Secretary of Commerce and Deputy Director of the USPTO, stated:

[1/] Teva also posits that the Supreme Court's decision to accept certiorari in MedImmune, Inc. v. Genentech, 427 F.3d 958 (Fed. Cir. 2005), cert. granted, 126 S. Ct. 1329 (U.S. Feb. 21, 2006), "places squarely before the Supreme Court whether the 'reasonable apprehension' test is required to establish an 'actual controversy.'" (Teva's Br. at 33). Teva's position is untenable. The declaratory judgment in MedImmune involves a patent that is the subject of a license between the parties -- the case before the Court does not involve a patent that is being litigated within the Hatch-Waxman statutory scheme. The Supreme Court's action on MedImmune will not affect the instant case -- it has nothing to do with the Federal Circuit's Teva v. Pfizer jurisprudence that a reasonable apprehension of imminent suit is a constitutional requirement that must be met in ANDA cases.

> Setting aside the constitutional concerns, the proposed amendment to establish an "actual controversy" for declaratory judgment subject matter purposes could undermine the patent system. In these cases the proposed amendment provides the generics with automatic grounds for a declaratory judgment action. This right to a declaratory judgment action could result in unnecessary harassment of patent owners. This is problematic for a number of reasons.
>
> First, the patent owner would have to bear significant litigation costs, which ultimately may be passed on to the consumer in the form of higher drug prices. Second, a statutory entitlement to a declaratory judgment action may create patent uncertainty. By lowering the threshold for challenging a patent, the patent owner would be subject to extra litigation, which often places a "cloud" on the patent's validity. This uncertainty would make it more difficult and risky for patent owners to market, commercialize, and license their pharmaceutical innovations, thereby reducing access to valuable new medicines and therapies.

Examining the Senate and House Versions of the 'Greater Access to Affordable Pharmaceuticals Act', 108th Cong. (2003) (statement of Jon W. Dudas, Deputy Under Secretary of Commerce for Intellectual Property, Department of Commerce).

Finally, Teva suggests that the Hatch-Waxman Act's "Civil Action To Obtain Patent Certainty" would be meaningless unless interpreted to confer automatic declaratory judgment jurisdiction. (Teva's Br. at 34). Teva

conveniently ignores the fact that the Act's "Civil Action To Obtain Patent Certainty" actually has the purpose of restricting declaratory judgment jurisdiction -- no suit for declaratory judgment of non-infringement may be brought under the Act's "Civil Action To Obtain Patent Certainty" unless the generic drug maker first gives the patent owner access to its ANDA.

B. Teva's Misplaced Reliance On The Teva v. Pfizer Factors

Teva first argues that at least three of the factors this Court found relevant to Teva's reasonable apprehension in Teva v. Pfizer, 395 F.3d at 1333, 1334, are present, and relevant, in this case:

(1) Teva asserts that Novartis' "Listing of [the DJ] Patents in the Orange Book" establishes a reasonable apprehension of suit. (Teva's Br. at 29). Teva's position is erroneous. Recognizing that the listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement, this Court categorically stated:

> [w]e are not prepared to hold that listing a patent in the Orange Book evidences an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

Teva v. Pfizer, 395 F.3d at 1333.

Plainly, this factor is entitled to little weight since Novartis is required to list its patents in the Orange Book and its intent to sue on those patents cannot be gleaned from that mandatory listing.

(2) Teva further asserts that "Novartis' consistent historic aggressiveness against Teva and other generic companies" further increases Teva's apprehension of suit on the DJ patents. Of course, Novartis' membership in an industry that diligently protects its patent portfolios should not be construed as a threat of suit on the DJ patents which Novartis has never asserted against any defendant.

(3) Finally, Teva points to Novartis' "refusal to provide a covenant not to sue" on the DJ patents. (Teva's Br. at 26). Teva should not be allowed to shift its burden of proving jurisdiction onto Novartis by demanding a covenant not to sue and then claiming an apprehension of imminent suit when Novartis declines to give it. That would be nonsensical. Although a covenant not to sue should provide Teva with the highest level of comfort, the lack of a covenant not to sue cannot evidence the imminency of any potential infringement suit.

* * *

In sum, even when added together, these three factors are plainly insufficient to establish reasonable apprehension of imminent suit. Teva v. Pfizer, 395 F.3d at 1333-34.

C. Other Teva v. Pfizer Factors Are Absent In This Case

Teva fails to mention that other factors favoring jurisdiction were present in Teva v. Pfizer, but are not present in this case. First, Pfizer had already sued Ivax, the first generic ANDA filer, for infringement of the same patents subsequently included in Teva's declaratory judgment action. Id. at 1330. In this case, Novartis has never sued anyone on the DJ patents or on the foreign counterparts to the DJ patents.

Second, in Teva v. Pfizer, Teva argued that Pfizer's suit against Ivax, followed by Pfizer's settlement with Ivax, left a "cloud of litigation" hanging over Teva. Id. at 1331. In this case, Teva is the first filer and Teva has in fact been sued by Novartis on the basic famciclovir patent. There is no "cloud" over Teva in this case because Teva is already "in the litigation" and has presumably qualified for the 180 days of marketing exclusivity.

D. Novartis' Prior Suit On The '937 Patent Cannot Carry The Day For Teva

Teva next turns to Novartis' prior suit on the '937 patent and argues that Novartis' action in bringing that suit ensures that Teva has sufficient apprehension to warrant declaratory judgment jurisdiction. First, Teva argues that the case law provides for automatic declaratory judgment jurisdiction when there has been a prior suit. That is certainly not the case. Second, Teva argues that under the particular facts of this case, Novartis' prior suit on the '937 patent must be awarded great weight under the totality of the circumstances, thus ensuring sufficient reasonable apprehension of suit on the DJ patents. This theory must also fail.

1. Teva's Case Law Does Not Provide Automatic Jurisdiction

Teva argues that the case law has created an automatic holding of reasonable apprehension where the declaratory judgment action follows a first suit by the declaratory judgment defendant. In support, Teva cites to a number of ANDA and non-ANDA cases in which the declaratory judgment defendant had already sued the plaintiff and in which the court found jurisdiction.

As demonstrated below, Teva's cases do not stand for such a sweeping proposition. Rather, the courts in these cases conducted careful analyses

under the totality of the circumstances, according the prior suits appropriate weight. Based on a weighing of all factors, the courts concluded that under the particular circumstances present in those cases, a reasonable apprehension did exist.

a. The Goodyear Tire And Vanguard Research Cases

Teva first relies on the Federal Circuit decisions in Goodyear Tire & Rubber Co. v. Releasomers Inc., 824 F.2d 953 (Fed. Cir. 1987), and Vanguard Research Inc. v. PEAT Inc., 304 F.3d 1249 (Fed. Cir. 2002), for its proposition that a prior suit automatically gives rise to declaratory judgment jurisdiction. Of course, that is not what these non-ANDA cases say. Rather, the prior trade secret misappropriation lawsuit in each case was properly considered by the Court during its analysis of the totality of the circumstances. In each case, the Court's analysis of all the factors led to its finding of reasonable apprehension. In each case, the Court gave weight to the prior suit. In each case, the Court also gave weight to additional factors (see below).

The totality of the circumstances in non-ANDA cases such as these may or may not be directly comparable to the circumstances of an ANDA case -- consider that it may be more reasonable to fear suit where the patents cover technology for which one has already been sued for trade secret misappropriation,

than where the patent owner is forced, within a specific narrow time frame, to consider all the arguments against his patents, at the end of which he elects to sue on some, but not all, of them.

The present case falls squarely within the regulated statutory framework of the Hatch-Waxman Act -- a framework that requires a statutory listing of patents, defines strict protocols for attacking one or more of the listed patents and allows a statutory 45-day time period to bring suit on one or more of the attacked patents. In this case, Novartis used the 45 days provided by the Hatch-Waxman Act to study Teva's certifications attacking all five listed patents and the reasoning behind them. Within 45 days, Novartis elected to sue on only one of the patents certified to by Teva -- the basic patent covering famciclovir and its use for treating viral infections.

Novartis postulates that caution must be used in assigning weight to a prior suit in the ANDA context -- in particular the court must not fail to consider the statutory Hatch-Waxman scheme with its host of mechanical obligations regarding patents and the impact of that scheme on the particular patents at issue.

(i) Goodyear Tire v. Releasomers

In Goodyear, 824 F. 2d at 954, the patent owner, Releasomers, had already sued Goodyear for trade secret misappropriation. Under the totality of the

circumstances, the Court concluded that Goodyear had reasonable apprehension of being sued on Releasomer's patents because they claimed "essentially the same technology involved in the state trade secret litigation." Id. at 956. Of course, the Court also considered the fact that when Releasomers' patents first issued, a representative from Releasomers said that Releasomers and Goodyear "would have to talk about infringement of the patents by Goodyear and possible licensing since Goodyear might be liable for past patent infringement," and that "the parties might wind up in Federal Court on these issues." Id. at 956 n.5. Finally, the Court referred to the following ominous statement made by Releasomers' counsel during oral argument:

> [Releasomers] would attempt to discover whether appellant was infringing the patents and, once it determined that in its view Goodyear was infringing, 'I [counsel] would have no hesitation whatsoever of bringing about a lawsuit.'

Id. at 956 (emphasis added).

(ii) Vanguard Research v. PEAT

In Vanguard, 304 F. 3d at 1251, the patent owner, PEAT, had already sued Vanguard for trade secret misappropriation. Vanguard then sought a declaratory judgment on a corresponding PEAT patent, arguing that Vanguard was under reasonable apprehension that PEAT would ultimately sue on that patent. Id.

at 1251-52. Under the totality of the circumstances, the court concluded that Vanguard had reasonable apprehension of being sued on PEAT's patent -- a patent the court characterized as relating to the "same technology" as the trade secrets. Id. at 1255.

Of course, the Court also considered the following additional facts: The parties had enjoyed an extensive marketing partnership that had gone sour. Id. at 1250-51. After PEAT had sued Vanguard in state court, and after Vanguard had brought its declaratory judgment action, PEAT then wrote Vanguard that it no longer had the right to market PEAT's technology or to use it for the development of future contracts. Id. at 1254. Moreover, PEAT repeatedly implied to a Vanguard client that "Vanguard was using the PEAT technology without a license." Id. at 1255.

b. Alza Corp. v. Impax Laboratories

Teva points to Alza Corp. v. Impax Laboratories, Inc., No. C-3-4032-VRW, slip. op. at 20-23 (N.D. Cal. April 19, 2004) (A262), as teaching that a prior suit inevitably leads to declaratory judgment jurisdiction. In that case, Alza had listed three patent "families" in the Orange Book for its drug Ditropan XL. (A266). Each patent "family" included patents of the same inventors that were part of the same chain of patent applications. (A266). Upon receipt of Impax's

Paragraph IV Certification on five of the Alza patents (belonging to the "Guittard" family of patents), Alza sued Impax on only one of them. (A266). The patent Alza sued on had issued from the USPTO only after Alza had filed a terminal disclaimer. (A283). The earlier Guittard patent which was the impetus for the terminal disclaimer, as well as two other Guittard patents also terminally disclaimed for the same reasons, were the subject of Impax's subsequent declaratory judgment action. (A267). Under the totality of the circumstances, the Court concluded that the asserted and non-asserted Guittard patents covered "similar (if not the same) technology" and held that Impax had reasonable apprehension of suit on the other Guittard patents. (A283).

Here, the DJ patents did not issue from applications that were related to the '937 patent, nor did the USPTO require that any of them be terminally disclaimed over the '937 patent.

c. Kos Pharmaceuticals v. Barr Laboratories

Teva points to Kos Pharmaceuticals v. Barr Laboratories, 242 F. Supp. 2d 311 (S.D.N.Y. 2003), as teaching that a prior suit inevitably leads to declaratory judgment jurisdiction. In considering the totality of the circumstances, the Court held that the non-asserted patents (which were not listed in the Orange Book) were "not just similar, but nearly identical" to the ones that Kos had already

sued on -- both the asserted and non-asserted patents were directed to a composition containing nicotinic acid and a time-release process with little or no liver damage. Id. at 316. In fact, in a later decision, the Court further explained its understanding that the asserted and non-asserted patents "vary[] only as to quantities." Kos Pharms. v. Barr Labs., 218 F.R.D. 387, 391 (S.D.N.Y. 2003). Finally, the Court considered that the CEO of Kos had declared in a press release that Kos would "vigorously enforce [its] patent rights in order to protect Kos's . . . products." Kos, 242 F. Supp. 2d at 316. The Court held that Barr had reasonable apprehension of being sued on the non-asserted patents. Id. at 315.

Here, the DJ patents are not "nearly identical" to the '937 patent, and Novartis has made no press release threatening suit on them.

d. Clonetech Laboratories v. Life Technologies

Teva points to Clonetech Laboratories v. Life Technologies, 2000 U.S. Dist. LEXIS 19320 at *1 (D. Md. Dec. 19, 2000), as teaching that a prior suit inevitably leads to declaratory judgment jurisdiction. The Clonetech patents relate to cloned genes, subject matter that falls outside of the Hatch-Waxman Act and its requirements for listing patents and filing suits. Id. at *2-3. The patent owner, Life Technologies, had sued Clonetech for infringement of two patents. Id. Life Technologies did not assert a third patent against Clonetech even though it issued

from the same patent chain as the two patents sued on. Id. Clonetech brought a declaratory judgment action on the third patent. Id. Finding reasonable apprehension under the totality of the circumstances, the Court pointed not only to the similarities in the patents, but also to the fact that Life Technologies had publicly stated that the third, non-asserted patent "re-establishes our proprietary position with respect to [the technology at issue]", and that Life Technologies had asserted the third patent against two other companies which it had already sued for infringing the two asserted patents. Id. at *7.

Here, Novartis has made no public statement regarding the merit of the DJ patents, and has not asserted the DJ patents against anyone.

e. Teva Pharmaceuticals, USA v. Abbott Laboratories

Finally, Teva points to Teva Pharmaceuticals, USA Inc. v. Abbott Laboratories, 301 F. Supp. 2d 819 (N.D. Ill. 2004), as teaching that a prior suit inevitably leads to declaratory judgment jurisdiction. Biaxin, the drug at issue in that case, was an antibiotic -- at the time Teva filed its ANDA, antibiotics were exempt from the certification and Orange Book listing requirements of the Hatch-Waxman Act. Id. at 828. Abbott, therefore, had not been required to select patents to sue on in 45 days because Teva had submitted no notice of invalidity or non-infringement.

Teva brought a declaratory judgment action on three Abbott patents. Id. at 820. Under the totality of the circumstances, the Court found that Teva had reasonable apprehension of being sued on the Abbott patents. Id. at 825-26. In its analysis, the Court considered not only Abbott's general litigious nature and its refusal to provide a covenant not to sue, but also the important fact that Abbott had previously brought a regulatory proceeding against Teva and four other generic manufacturers in Canada on the Canadian patent covering its Biaxin product. Id. at 820-21. Undoubtedly, the Court accorded substantial weight to the Canadian proceedings, id. at 823-24, because each of the U.S. Patents and the Canadian patent included claims to the crystal forms of clarithromycin, the active ingredient in Biaxin. Id. at 820. Moreover, the patent involved in the Canadian proceedings was the foreign counterpart to one of the U.S. declaratory judgment patents, and included identical claims. (A329–42; A343–73).

Here, Teva has never suggested that Novartis has asserted or threatened to assert its foreign counterparts of the DJ patents against Teva, or against anyone else.[2/] Indeed, subsequent to the district court briefing period in this case, Novartis did not assert its Canadian counterpart patent to two of the DJ

[2/] Teva is certainly aware of that fact and therefore should not dispute it.

patents within the permitted 45 day period in response to a Notice of Allegation served by Teva in Canada. (A374-79).

2. Novartis' Prior Suit On Only The '937 Patent Should Have No Weight Under The Totality Of The Circumstances

Novartis carefully considered Teva's Paragraph IV Certifications attacking all of Novartis' Famvir® patents in the 45 days after receiving notice of them and then elected to sue only on the '937 patent. The import of these actions is plain. They can only serve to minimize -- if not eliminate -- any apprehension on Teva's part that it will be sued on the DJ patents in the immediate future. Of course, Novartis' actions in this regard were the principal reason that the Court below dismissed Teva's declaratory judgment action. After listening to Teva argue that it would be a "logical step" for Novartis to sue on the DJ patents in the future, the Court rejected that notion:

> It is also of no moment, although filing a suit may be another logical step, there is no indication in this case that such a suit is in fact imminent. The facts of this case in fact indicate the opposite. Defendant in fact could have sued under four method patents on the drug in the case presently pending before Judge Cavanaugh and chose not to do so and in fact allowed the 45-day window to expire.

(A11 at line 8-15).

Novartis' failure to sue on the DJ patents in the 45-day window, coupled with the fact that the '937 patent and the DJ patents cover different inventions, cannot provide Teva apprehension of suit. To the contrary, these circumstances provide only reasonable comfort of no suit. Novartis' prior suit should be accorded little, if any, weight under the totality of the circumstances.

Indeed, if a suit on one Orange Book patent gives rise to reasonable apprehension of suit on all non-asserted Orange Book patents (certified to under Paragraph IV), then the statute would not permit a selection at all -- rather, it would provide only two options: no suit, or suit on all patents.[3/]

IV. Teva's Other Theories That Attempt To Abolish Reasonable Apprehension Have No Merit

First, Teva cites Maryland Casualty, 312 U.S. at 270, for the proposition that if a claim by Novartis against Teva would be justiciable, then Teva's claim for declaratory relief must be justiciable as well. It does this by cherry-picking a quote from Maryland and then ignoring the facts that made the

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[3/] To the extent Teva suggests that the District Court was wrong because of specific "experiences" Teva has learned about where brand name companies have refrained from suing on all Orange Book patents so that one or more patents can nefariously be held in reserve until a later, more opportune time (Teva's Br. at 16), it turns out that Teva knows of no such "experiences" -- instead it is merely referring to the remarks of Senator Kennedy, who in turn is simply guessing what some companies may do. (Teva's Br. at 17, 18).

Supreme Court declare that an actual controversy existed in that case. Maryland does not support Teva's assertion -- the Court found a justiciable controversy because it recognized that the declaratory judgment plaintiff, an insurance company, may be required to pay an injured third party on an insurance policy that was already being litigated in two prior cases: first, in state court between the insured and third party with respect to liability, and second, in a declaratory judgment suit by the insurer against the insured in federal court. Id. at 273-74. As several subsequent decisions have recognized, an actual controversy existed because if the third party prevailed in the state court suit, it had a statutory right to proceed against the insurance company in a supplemental proceeding. See e.g., Allendale Mut. Ins. v. Kaiser Eng'rs, 804 F.2d 592, 594-95 (10th Cir. 1986). The Court explained that if it held that there was no jurisdiction, "it is possible that opposite interpretations of the policy might be announced by the federal and state courts." Maryland Cas., 312 U.S. at 274. The Court was concerned about inconsistent results in on-going related suits. In contrast, dismissing Teva's suit causes no such risk because a decision on the four method patents is not necessary to avoid inconsistent results on the '937 patent litigation.

Second, Teva contends that its declaratory judgment action is justiciable because all of the acts necessary for resolution of the merits of the

claim occurred prior to filing its declaratory judgment complaint. This unique theory is likewise not supported by the cases Teva cites. Rowan Co. v. Griffin, 876 F.2d 26 (5th Cir. 1989); Salomon Bros., Inc. v. Carey, 556 F. Supp. 499 (S.D.N.Y. 1983). These cases address liability under existing contractual duties and neither falls within the Hatch-Waxman statutory scheme.

In Rowan, the defendant Griffin was injured while working for Rowan. Rowan began paying maintenance and cure to Griffin. Rowan, 876 F.2d at 27. Griffin then received a physician's report that he had made a full recovery. Id. Rowan sought a declaration of its obligation with respect to future maintenance and cure. Id. The appellate court explained that a demand from Griffin for future payments was not required before a justiciable controversy could be found. Id. at 28. The appellate court explained that the dispute presented by this declaratory judgment action was "whether Rowan's legal obligation to provide Griffin with maintenance and cure has been extinguished . . . ." Id. at 28 (emphasis added).

Similarly, in Salomon, the parties had entered into a written customer agreement regarding the sale of securities. Salomon, 556 F. Supp. at 500. Carey, the customer, had his attorney write a letter to Salomon Brothers stating that Carey had the basis of a lawsuit for breach of that agreement and for breach of fiduciary

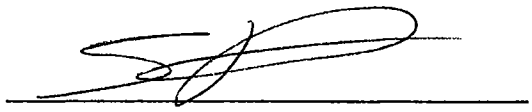
duties. Id. The Court explained that there was a substantial controversy "with respect to the performance of Salomon Brothers under its customer agreement with Carey . . . since Carey asserts legally cognizable claims sounding in contract and agency law and Salomon Brothers asserts a number of defenses denying liability for any damages." Id. at 501. The Court even noted that Carey was able to define his monetary damages in his complaint which resulted from the alleged breaches. Id.

In contrast, Teva is not seeking a determination of whether its on-going contractual obligations are extinguished. Without any action by Novartis, Teva seeks an independent declaration on Novartis' method patents in the first instance. Teva has pointed to no ANDA case which applies the rule it contends is applicable here.

CONCLUSION

For the reasons set forth in this brief, the Court should dismiss Teva's appeal and affirm the judgment of the district court dismissing Teva's declaratory judgment complaint. Should this Court determine that an actual controversy exists, the Court should remand to the district court to determine whether the district court should use its discretion to decline jurisdiction.

May 12, 2006



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CERTIFICATE OF SERVICE

United States Court of Appeals
for the Federal Circuit
No. 06-1181
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TEVA PHARMACEUTICALS
USA, INC.,
Plaintiff-Appellant,
v.
NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS PHARMA
AG, and NOVARTIS INTERNATIONAL
PHARMACEUTICAL LTD.,
Defendants-Appellees.
----------)

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

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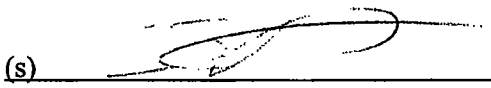
(s) 

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