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.

# CORRECTED BRIEF OF PLAINTIFF-APPELLANT, TEVA PHARMACEUTICALS USA, INC.


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March 30, 2006

*Certificate of Interest*

Counsel for the appellant certifies the following:

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

   Teva Pharmaceuticals USA, 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:

   Teva Pharmaceuticals USA, Inc.

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:

   Orvet UK Ltd.
   Teva Pharmaceuticals Europe (Holland)
   Teva Pharmaceutical Industries Ltd.

4. 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*

Defendants-appellees (collectively "Novartis") are prosecuting a related patent infringement action against plaintiff-appellant, Teva Pharmaceuticals USA, Inc. ("Teva") in the United States District Court for the District of New Jersey. *Novartis Pharmaceuticals Corp., et al. v. Teva Pharmaceuticals USA, Inc.,* C.A. 05-1887 DMC. In that action, Novartis claims that Teva infringed U.S. Patent No. 5,246,937 (the '937 patent) under 25 U.S.C. §271(e)(2) by filing an Abbreviated New Drug Application seeking FDA approval for a generic formulation of Novartis' Famvir® product. Novartis listed the '937 patent, along with four other patents, in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (a document generally referred to and referred to herein as the "Orange Book") as patents that "could reasonably be asserted" against an unauthorized generic form of Famvir®. The present action is a declaratory judgment action brought by Teva seeking a declaration that the other patents that Novartis listed in the Orange Book with respect to Famvir® are invalid, unenforceable and/or not infringed by Teva's generic formulation.

## *Jurisdictional Statement*

The District Court had subject matter jurisdiction in this case under 28 U.S.C. §§1331 and 1338(a) because the case involves substantial claims arising under the United States Patent Act, 35 U.S.C. §1 *et seq.*, under 28 U.S.C. §§2201 and 2202 because the case presents an actual controversy concerning the validity and/or infringement of the patents-in-suit, and under 21 U.S.C. §355(j)(5)(C)(i)(II) and 35 U.S.C. §271(e)(5) because it is a "civil action to obtain patent certainty" as provided in those statutes.

A final judgment in the District Court dismissing appellant's claims without prejudice for lack of subject matter jurisdiction was entered on December 12, 2005. (A copy of the District Court's opinion is set forth in Addendum A.) Teva filed a timely notice of appeal on January 10, 2006.

The jurisdiction of this Court is predicated upon 28 U.S.C. §1295(a)(1) because the appeal challenges a final decision of the United States District Court for the District of New Jersey in a case where the jurisdiction of that court was based, in whole or in part, upon 28 U.S.C. §1338 as a case relating to patents.

## *Statement of Issues*

Whether there is an "actual controversy" sufficient to support subject matter jurisdiction over Teva's claim for a declaration that certain patents

were invalid, unenforceable or not infringed where: (i) appellee listed the patents in the Orange Book with respect to its Famvir® product, thus representing that an infringement action under those patents "could reasonably be asserted" against any generic formulation of that drug; (ii) Teva committed a statutory act of infringing those patents under 35 U.S.C. §271(e)(2) by submitting an Abbreviated New Drug Application ("ANDA") to market a generic formulation of Famvir® before the expiration of the patents; (iii) Novartis sued Teva to prevent Teva from launching its generic formulation of Famvir® alleging that Teva's ANDA infringed another patent listed in the Orange Book with respect to Famvir®; (iv) appellee has consistently and aggressively enforced its pharmaceutical patents against Teva and other generic drug companies; and (v) appellee has refused to give any assurance that it would not sue Teva for infringement of the patents.

***Introduction***

Teva challenges the District Court's dismissal of its action for lack of an actual controversy as required by the Declaratory Judgment Act. Teva filed this action against Novartis seeking a declaration that four patents owned by Novartis were invalid, unenforceable, and/or not infringed by Teva's generic formulation of Famvir®, a profitable drug product marketed by Novartis prescribed for the treatment of various herpes virus infections.

The District Court found no actual controversy, even though only two months before Teva filed its complaint Novartis had brought a patent infringement action on a related patent against Teva to prevent Teva from launching its generic formulation of Famvir®. The District Court ruled that the divided panel decision of this Court in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), *rehearing en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) ("*Teva v. Pfizer*"), precluded the exercise of subject matter jurisdiction even though the pendency of Novartis' patent infringement claim against Teva involving the very same product clearly distinguished this case from *Teva v. Pfizer*. The District Court ruled that Teva did not face a "reasonable apprehension" of suit by Novartis on the four patents-in-suit (the "Related Patents") for seeking FDA approval for its generic product even though Novartis had already sued Teva for seeking such approval. (A11-12)

As explained below, Novartis' earlier commencement of patent infringement litigation against Teva, together with the other circumstances presented here, compels the conclusion that Teva did face and continues to face a reasonable apprehension that Novartis will bring an action for patent infringement on the Related Patents. This Court's decisions in *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249 (Fed. Cir. 2002), and *Goodyear*

*Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953 (Fed. Cir. 1987), are controlling in this regard. By invoking the '937 patent to delay Teva from introducing a generic product to compete with Famvir®, Novartis demonstrated that it was not one of the "quiescent patent owners" that the reasonable apprehension test was established by this Court to protect. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). It is fanciful to think that Novartis will not invoke the Related Patents to further delay generic competition regardless of the outcome of the litigation over the '937 patent. Since Teva has already committed an act of infringing the Related Patents, Novartis can commence such a claim at any time. The Related Patents present Teva with a "Damoclean threat with a sheathed sword" for which the Declaratory Judgment Act was enacted to address. *Id.* at 735.

Subject matter jurisdiction in this case is particularly warranted in light of the 2003 amendments to the Hatch-Waxman Act and the patent statutes. The *Teva v. Pfizer* majority expressed the view that, in enacting these amendments, Congress intended for this Court to continue to apply the reasonable apprehension test where a generic company brings a "civil action to obtain patent certainty" under 21 U.S.C. §355(j)(5)(C). The legislative history of these amendments shows that this case presents circumstances in

which Congress anticipated that a declaratory judgment would be available to the generic company. It is contrary to congressional intent — and common sense — not to resolve whether Teva's product infringes any of the other patents that Novartis listed in the Orange Book for Famvir®.

Finally, the issues that divided the *Teva v. Pfizer* panel and further divided the whole Federal Circuit in connection with the petition for rehearing en banc in that case remain in flux because the Supreme Court has granted review in another case in which this Court upheld the dismissal of a declaratory judgment action where the plaintiff was found unable to establish a reasonable apprehension of a patent infringement suit. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *cert. granted,* 74 U.S.L.W. 3471 (U.S. Feb. 21, 2006). By deciding this appeal on the basis of the principles followed in *Vanguard* and *Goodyear,* this Court can prudently avoid the need to address what remains a controversial constitutional issue.

## *Statement of Facts and of the Case*

Novartis is the holder of a New Drug Application ("NDA") for three strengths of Famvir®, a prescription drug that contains the active ingredient famciclovir and is used for the treatment of various herpes virus infections. Novartis listed five patents in the FDA's *Approved Drug Products with*

*Therapeutic Equivalence Evaluations* (a document generally referred to as the "Orange Book") with respect to Famvir®. By listing these patents in the Orange Book, Novartis affirmatively represented that a claim for infringing any of the listed patents "could reasonably be asserted" against any company that sells a generic famciclovir product without a license from Novartis. 21 U.S.C. §355(b)(1).

The five listed patents are all directed to famciclovir and therapeutic uses for that drug:

- U.S. Patent No. 5,246,937 (the "'937 patent") is directed to a class of compounds, including famciclovir, and methods of treating viral infections, including herpes virus infection, using such compounds. (A117-130)
- U.S. Patent No. 5,840,763 (the "'763 patent") is directed to methods of preventing or reducing reactivation of latent herpes infection with famciclovir. (A19-22)
- U.S. Patent No. 5,866,581 (the "'581 patent") is directed to the treatment of post-herpetic neuralgia (a complication of herpes infection) with famciclovir. (A23-33)
- U.S. Patent No. 5,916,893 (the "'893 patent") is directed to the prevention, reduction or treatment of latent herpes infection with famciclovir. (A34-38)
- U.S. Patent No. 6,124,304 (the "'304 patent") is directed to the treatment of zoster associated pain and post-herpetic neuralgia (both complications of herpes infection) with famciclovir. (A39-48)

The '937 patent expires on September 21, 2010. The '581 and '304 patents expire on October 4, 2014. The '763 and '893 patents expire on September 1, 2015. The '763, '581, '893 and '304 patents are the "Related Patents."

On December 28, 2004, Teva filed an Abbreviated New Drug Application with the FDA seeking approval to sell generic famciclovir tablets before the expiration of the patents listed by Novartis in the Orange Book. (A52) Teva certified under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that all five listed patents were invalid and/or would not be infringed by the generic product for which Teva sought FDA approval (the "Paragraph IV certification"). (A52) The filing of the ANDA with a Paragraph IV certification constituted an act of infringing all five patents, entitling Novartis to sue Teva immediately for infringement. 35 U.S.C. §271(e)(1).

Novartis sued Teva on April 8, 2005, claiming that Teva's ANDA infringed the '937 patent under 35 U.S.C. §271(e). (A186-193) Novartis sought to prevent FDA approval of Teva's ANDA before the expiration of the '937 patent. Because Novartis commenced this action within 45 days of Teva's Paragraph IV certification, FDA approval of Teva's ANDA was automatically stayed until a court decision that the '937 patent is invalid or

not infringed or the passage of 30 months from the commencement of the suit, whichever first occurs. 21 U.S.C. §355(j)(5)(B)(iii).[1]

Novartis' decision to sue on only one of the patents listed in the Orange Book did not affect the 30 month stay. Suing on only one of the listed patents triggered the same stay of FDA approval of Teva's ANDA that suing on all five or any subset would have triggered. Novartis has evidently decided to hold the Related Patents in reserve in the hope of asserting them at a later time if, for example, Teva were to prevail in the suit brought on the '937 patent. Moreover, the Related Patents have expiration dates four or five years later than the '937 patent. By suing on the Related Patents, Novartis would run the risk that Teva would prevail on some or all of them before the '937 patent expired and thereby put itself in a position to launch its generic product sooner without risking damages for patent infringement. By bringing suit on the '937 patent alone in the first instance, Novartis has sought to put Teva to the hard choice of either launching at risk of massive liability for patent infringement when the '937 patent expires or Teva

[1] The 30 month stay can be adjusted by the district court if a party fails to cooperate in expediting the litigation. 21 U.S.C. §355(j)(5)(B)(iii).

prevails in the pending infringement action,[2] or foregoing that opportunity and thereby effectively extending the term of the '937 patent.

Since Novartis did not assert claims within 45 days on the Related Patents, Teva was authorized to bring a "civil action to obtain patent certainty" under 21 U.S.C. §355(j)(5)(C) and 35 U.S.C. §271(e)(5), statutory provisions added by Congress in 2003. Teva brought such an action in the United States District Court for the District of New Jersey on June 3, 2005. (A49-62) As explained below, Congress established the cause of action that Teva asserted here precisely to provide generic companies such as Teva the opportunity to obtain "patent certainty" without the need to launch at risk of liability for damages.

Novartis moved to dismiss Teva's complaint for lack of subject matter jurisdiction on August 15, 2005, arguing that Teva could have no reasonable apprehension that it would be sued by Novartis for infringing the Related Patents. (A63) In response, Teva argued that Novartis had already sued Teva for patent infringement to forestall the launch of a generic competitor to Famvir® and predicated its infringement claim on the same conduct —

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[2] In 2005, Novartis generated $151 million in U.S. sales of Famvir®, and $254 million worldwide. 2005 Novartis Annual Report at 121. This report can be found online at (http://www.novartis.com/downloads_new/investors/AR05_E.pdf) (visited March 17, 2006).

Teva's ANDA submission with a Paragraph IV certification — that also constituted an act of infringing the Related Patents.

In addition, Teva proffered undisputed evidence to establish that (i) by listing the Related Patents in the Orange Book, as a matter of law Novartis represented that a claim for infringing each of them could reasonably be asserted against any generic form of Famvir®, (ii) Novartis had a history of frequently and aggressively suing generic drug companies to enforce its pharmaceutical patents (more than two dozen in the prior five years alone, including at least three suits against Teva since 2004), and (iii) Novartis expressly declined Teva's request for a covenant not to sue on the Related Patents. Novartis did not dispute this evidence, but argued that as a matter of law the record did not establish a basis for a reasonable apprehension of suit.

On December 12, 2005, the District Court granted Novartis' motion and dismissed the complaint. (A1) Teva filed a timely notice of appeal on January 10, 2006. (A17)

### *Summary of Argument*

Teva has sought a declaration concerning a claim for patent infringement that has fully accrued. All of the acts on which the resolution of that claim depends have already occurred. There is no question that

Novartis has a justiciable claim for patent infringement against Teva. Since the Supreme Court has ruled that the justiciability of a dispute does not depend on which party initiates its judicial resolution, Teva's claim for declaratory relief presents an "actual controversy."

Moreover, this Court's traditional two-part test for the existence of an actual controversy is satisfied as well. It is undisputed that Teva has actually committed an act of infringing the Related Patents, so the controversy is not abstract or hypothetical. In addition, Teva faces a reasonable apprehension that Novartis will sue for infringing the Related Patents. Novartis has already brought suit against Teva to forestall Teva's sale of the commercial technology generally covered by the Related Patents. Under the authority of *Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249 (Fed. Cir. 2002), and *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953 (Fed. Cir. 1987), the reasonable apprehension test is satisfied here.

This conclusion is buttressed by the additional circumstances that point to a reasonable apprehension of suit. Novartis has refused to supply Teva with a covenant not to sue on the Related Patents. (A223) It has aggressively pursued patent infringement claims against Teva and other generic drug companies. (A210-211) It has represented to the world that any unauthorized generic formulation of Famvir® would infringe the Related

Patents. These factors, all relevant to the "reasonable apprehension" inquiry, coupled with the pendency of Novartis' claim under the '937 patent, compel the conclusion that Teva has established a reasonable apprehension of suit.

***Argument***

## I. Standard of Review

The existence of an "actual controversy" sufficient to sustain federal subject matter jurisdiction in a declaratory judgment action is a question of law, reviewed by this Court *de novo. Teva v. Pfizer,* 395 F.3d at 1332; *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.,* 62 F.3d 1397, 1401 (Fed. Cir. 1995).

## II. An "Actual Controversy" Exists Between Teva And Novartis With Respect To The Related Patents.

### *A. Civil actions to obtain patent certainty under the Hatch-Waxman act.*

The Hatch-Waxman Act,[3] enacted in 1984, sought to accelerate the introduction of generic drugs. To this end, the Act allowed generic drug manufacturers to obtain faster FDA approval for their drugs by filing an Abbreviated New Drug Application or "ANDA." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). If the ANDA establishes that the

[3] Formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

generic drug has the same active ingredient as a drug that has been approved by the FDA (the "reference drug," here Famvir®) and is bioequivalent to that drug, the applicant can rely on the safety and efficacy data contained in the NDA for the reference drug. 21 U.S.C. §§355(j)(2)(A)(ii), (iv).

Virtually all new drugs are protected by patents. Congress recognized that uncertainty regarding the validity and scope of pharmaceutical patents would discourage investment in generic drug development and thereby inhibit the rapid introduction of generic drugs that Congress deemed essential to control the escalating cost of health care in the U.S. Accordingly, the Hatch-Waxman Act made provision for early judicial resolution of such uncertainty. As this Court observed:

> The [Hatch-Waxman] Act . . . sought to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products. In particular, the Act required NDA applicants to identify any patent that claims the drug that is the subject of the NDA or that claims 'a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted' against a party who made, used, or sold the drug. [21 U.S.C.] §355(b)(1). The statute directs the FDA to list the disclosed patents, *id.*, which the FDA does in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book." In addition, the Act requires an NDA holder to file for listing in the Orange

> Book any such patents that issue after the NDA is approved. Id. §355(c)(2).

*Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003).

An ANDA applicant must certify with respect to each patent listed in the Orange Book for the pertinent reference drug: (I) that the patentee has not filed the required patent information with the FDA, (II) that the patent has expired, (III) that the patent will expire on a specified future date, or (IV) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. §355(j)(2)(A)(vii). If the applicant certifies that the patent is invalid or not infringed — a "Paragraph IV certification" — it must send notice to the patentee setting forth the factual and legal bases for the certification. 21 U.S.C. §355(j)(2)(B).

The filing of an ANDA with a Paragraph IV certification for a generic formulation of a reference drug constitutes an act of infringing every one of the patents listed in the Orange Book with respect to that drug. 35 U.S.C. §271(e)(2). Congress provided that such a submission would constitute an act of infringing the listed patents to ensure the existence of a justiciable case or controversy to resolve legal questions concerning the validity and scope of those patents on a proposed generic formulation. *Eli Lilly*, 496 U.S. at 678; *Apotex*, 347 F.3d at 1339. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110

F.3d 1562, 1569 (Fed. Cir. 1997), this Court noted that the Act "provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve ***any*** dispute concerning infringement and validity." (emphasis added).

Congress not only permitted, but also encouraged patentees to bring infringement actions promptly after receiving a Paragraph IV certification. If the patentee brings its infringement action within 45 days of receiving the certification, then the FDA may not finally approve the ANDA for a period of 30 months, unless the infringement action is earlier resolved against the patentee. 21 U.S.C. §355(j)(5)(B)(iii). Failure to bring suit within 45 days permits the FDA to approve the ANDA application immediately upon the applicant's satisfaction of regulatory requirements. *Id.*[4] By suing on only one of the patents listed in the Orange Book, Novartis seeks to obtain the Hatch-Waxman Act's reward for prompt resolution of patent disputes (i.e. the 30-month stay of FDA approval) while leaving most of the patent disputes unresolved.

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[4] However, failure to sue within 45 days does not preclude suit under 35 U.S.C. §271(e) thereafter. Section 271(e)(2) provides that the filing of an ANDA with a Paragraph IV certification shall constitute an "act of infringement," but does not set forth any time limit for the patentee to assert an infringement claim. The District Court's suggestion that Novartis had allowed a "window" in which to sue on the Related Patents to "expire" is incorrect. (A11-12) The 45-day "window concerned only

*(continued on next page)*

Despite Congress' attempt to encourage early resolution of disputes concerning Orange Book patents, experience since the enactment of the Hatch-Waxman Act in 1984 showed that it is in the economic interest of some Orange Book patentees to defer asserting immediate infringement actions that they fully intended to prosecute at a more strategically advantageous time. For example, patentees often list more than one patent in the Orange Book with respect to a particular drug, just as Novartis has done in this case. The commencement of an infringement suit on any one of the patents within 45 days of receiving an ANDA applicant's Paragraph IV certification triggers the 30-month stay of FDA approval of the ANDA. By suing on only some of the listed patents while holding others in reserve, patentees position themselves to bring a later suit on the reserved patents in the event that the ANDA applicant successfully defends the initial infringement suit and threatens an immediate launch of its generic product.

In 2003, Congress sought to prevent patentees from gaming the system in this fashion by creating a "civil action to obtain patent certainty" as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Amendments"), P.L. No. 108-173,

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the 30 month stay of FDA approval and Novartis' suit on the '937 patent triggered that stay.

§1101(a)(2)(C), codified at 21 U.S.C. §355(j)(5)(C). The amendment specifically permits an ANDA applicant to "bring a civil action" under 28 U.S.C. §2201 "against the owner [of a patent listed in the Orange Book] or holder [of an NDA with respect to the reference drug] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval" if the patentee has not brought an infringement action within 45 days. 21 U.S.C. §355(j)(5)(C)(i)(II). Congress directed federal courts to exercise jurisdiction in all such actions "to the extent consistent with the Constitution." 35 U.S.C. §271(e)(5).

The legislative history of these provisions makes it clear that Congress intended it to apply where, as here, the patentee has brought an action against the ANDA applicant on fewer than all of the patents listed in the Orange Book. During the congressional debate, members of Congress identified a number of situations in which they expected courts to find the existence of a justiciable "case or controversy" sufficient to support a declaratory judgment action notwithstanding the patentee's failure to bring an infringement action within 45 days. One senator identified the precise situation presented here:

> For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's

> interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).

A decision of a patentee, like Novartis' decision here, to hold available infringement claims in reserve is thus the kind of "improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies" that Congress meant to address by creating a "civil action to obtain patent certainty." H.R. Conf. Rep. No. 108-391 at 836 (2003). The conference committee report that accompanied the Medicare Amendments set forth the conferees' expectation that courts would "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" in order to thwart these improper efforts. *Id.* The legislative history thus demonstrates that Congress expected that the

"reasonable apprehension" test would be satisfied in the circumstances presented in this case.

The precedents of the Supreme Court and this Court compel the same conclusion, as demonstrated in the next section of this brief.

### *B. Teva Has Established An Actual Controversy Under Traditional Tests Applied In Declaratory Judgment Actions.*

#### *1. Since a justiciable patent infringement claim has accrued between Teva and Novartis concerning the Related Patents, Teva has asserted an "actual controversy" under the Declaratory Judgment Act.*

The fact that Teva has already committed an act of infringement and a claim for patent infringement has fully accrued is a highly significant factor in determining whether there is an "actual controversy." "There is little difficulty in finding an actual controversy if all the acts that are alleged to create liability already have occurred." 10B C. Wright, *et al.*, FEDERAL PRACTICE AND PROCEDURE §2757, at 475 (1998). Where, as here, "all of the acts necessary for the resolution of the merits of the claim ... occurred prior to the filing of the [declaratory judgment] complaint," then the controversy is "real, definite, and concrete, and therefore justiciable." *Rowan Cos., Inc. v. Griffin*, 876 F.2d 26, 28 (5th Cir. 1989); *accord, Salomon Bros., Inc. v. Carey*, 556 F. Supp. 499, 501 (S.D.N.Y. 1983).

There is no question that if Novartis brought an action for patent infringement against Teva under 35 U.S.C. §271(e)(2), the case would present a justiciable controversy. Such claims are routinely entertained by district courts and reviewed by this Court. Every act needed to resolve such infringement claims will have already occurred by the time the patentee brings suit.

If such a claim by Novartis against Teva for infringing the Related Patents would be justiciable, then Teva's claim for declaratory relief must be justiciable as well. The Supreme Court has made it clear that "[i]t is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; *the inquiry is the same in either case.*" *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (emphasis added).[5] Thus, the dispute concerning the validity of the Related Patents and their infringement by Teva's generic formulation is justiciable whether the resolution of that dispute is initiated by Novartis or by Teva.

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[5] Indeed, the Supreme Court in *Maryland Casualty* found an actual controversy even before the cause of action by the declaratory judgment defendant against the declaratory judgment plaintiff had accrued. In that case, a liability insurer brought an action against a person injured by an insured driver seeking a declaration of non-coverage. Since the lawsuit brought by the injured party against the insured remained pending, a direct action by that party against the insurer had not yet accrued. *See* 312 U.S. at 273.

2. *Teva faces a reasonable apprehension that Novartis will bring an infringement action on the Related Patents.*

Application of this Court's two-part test for determining the existence of an actual controversy when a plaintiff sues a patentee for a declaration of invalidity and/or non-infringement also requires the conclusion that there was subject matter jurisdiction in this case. This Court has formulated the test as follows:

> In the classic patent declaratory judgment suit, *i.e.*, where the declaratory plaintiff is laboring under the threat of litigation for alleged infringement of a patent, the "actual controversy" requirement means that there is jurisdiction over the action if: (1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues.

*Fina Oil & Chem. Co. v. Ewen,* 123 F.3d 1466, 1470 (Fed. Cir. 1997). This Court recognized in *Teva v. Pfizer* that submission of an ANDA with a Paragraph IV certification satisfies the first requirement. 395 F.3d at 1332. Teva has acted in a way that not only "could" but does constitute an act of infringement.

Moreover, the "reasonable apprehension" branch of this Court's test is satisfied here as well. The Court looks to the totality of the circumstances to determine whether a declaratory judgment plaintiff faces a reasonable

apprehension of being sued for patent infringement where there has been no express threat of litigation by the patentee. *Teva v. Pfizer,* 395 F.3d at 1333. The circumstances here warrant the conclusion that Teva can reasonably anticipate that Novartis will sue it for infringement of the Related Patents.

a. *Pending litigation against Teva's famciclovir ANDA.* The critical fact here is that Novartis has already sued Teva to prevent Teva's launching its generic famciclovir product. In *Arrowhead,* this Court explained that, while an express threat of patent litigation by the patentee establishes a reasonable apprehension of suit without more, the totality of the circumstances might establish a reasonable apprehension "in the absence of *any* communication" from the patentee to the declaratory judgment plaintiff. 846 F.2d at 736 (emphasis in original). But, if the patentee "has done nothing more but obtain a patent, there can be no basis for the required apprehension, *a rule that protects quiescent patent owners against unwarranted litigation.*" *Id.* (emphasis added).

A patentee that has already initiated litigation to forestall an alleged act of infringement by the declaratory judgment plaintiff is obviously no longer "quiescent," and in these circumstances, this Court has found a reasonable apprehension of infringement litigation. *See Vanguard Research, Inc. v. PEAT, Inc.,* 304 F.3d 1249 (Fed. Cir. 2002); *Goodyear Tire & Rubber*

*Co. v. Releasomers, Inc.*, 824 F.2d 953 (Fed. Cir. 1987). In both of these cases, the patentee had commenced litigation against the declaratory judgment plaintiff over "the commercial technology generally covered by" the patents that were the subject of the claim for declaratory relief. *Id.* at 955. *See Vanguard,* 304 F.3d at 1254-55 (relying on *Goodyear*). Where the patentee has "started it," the rationale for requiring further evidence that the patentee will pursue infringement claims all but disappears.

Although neither *Vanguard* nor *Goodyear* were ANDA cases, district courts in ANDA cases have applied those decisions to find an actual controversy in declaratory judgment action brought by ANDA applicants where the Orange Book patentee has commenced litigation against the ANDA applicant on related intellectual property. *See Alza Corp. v. Impax Laboratories, Inc.*, No. C-3-4032-VRW, slip op. at 20-23 (N. D. Cal., April 19, 2004) (A262); *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 315-16 (S.D.N.Y. 2003); *Clontech Labs., Inc. v. Life Techs., Inc.*, 2000 U.S. Dist. LEXIS 19320, at *5-6 (D. Md. Dec. 19, 2000). *See also Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 822 (N.D. Ill. 2004) (citing *Kos Pharms.*, 242 F. Supp. 2d at 315). More important, the Congressional Conference Committee report for the final version of the Medicare Amendments that established the "civil action for patent certainty"

specifically cited *Vanguard* to exemplify the application of the reasonable apprehension test that it expected courts to employ in weighing jurisdiction in such cases. H.R. Conf. Rep. No. 108-391, at 836 (2003).

*Vanguard* and *Goodyear* are controlling here. Teva's ANDA seeks FDA approval to market a generic formulation of famciclovir to treat various herpes infections. Novartis has sued Teva on a patent said to cover the use of famciclovir to treat herpes infections. The Related Patents also contain claims concerning the use of famciclovir to treat herpes infections and their complications. Since Novartis has already sued Teva over its generic famciclovir formulation, under the authority of *Vanguard* and *Goodyear* Teva faces an objectively reasonable apprehension that Novartis will bring suit on the Related Patents.

The District Court in this case did not discuss *Vanguard* or *Goodyear* in explaining its dismissal of Teva's complaint. Rather, that court relied on *Teva v. Pfizer* — finding the facts of this case "very similar" to those in *Teva v. Pfizer* — and on two decisions from other judges in the same district, *Dr. Reddy's v. Pfizer, Inc.*, 2003 U.S. Dist. LEXIS 24531 (D.N.J. July 8, 2003), and *Glaxo Group v. Dr. Reddy's Laboratories*, 325 F. Supp. 2d 502 (D.N.J. 2004). But none of the cases on which the District Court relied excused that court's disregard of *Vanguard* and *Goodyear*.

Nothing in *Teva v. Pfizer* called into question the continuing authority of those cases. The majority opinion specifically cited *Vanguard* as authoritative, 395 F.3d at 1337, and relied on the legislative history that cited *Vanguard* as exemplifying the application of the reasonable apprehension test, *id.* The Court distinguished *Vanguard* because, among other things, the patentee had brought earlier litigation against the declaratory judgment plaintiff in *Vanguard* but not in *Teva v. Pfizer, id.* n.9.[6] Since Novartis has brought such earlier litigation against Teva, it is *Vanguard* that controls.

Similarly, in *Dr. Reddy's v. Pfizer,* the patentee had not sued Dr. Reddy's with respect to its proposed generic product. Hence, that case, like *Teva v. Pfizer,* is distinguishable on a critical point.[7]

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[6] The majority also noted that the patentee had also notified Vanguard and a prospective Vanguard customer that Vanguard was not authorized to use its technology. However, Novartis' listing of the Related Patents in the Orange Book to give notice to the world that the Related Patents could "reasonably" support an infringement action against an unauthorized generic form of Famvir® plainly serves the same function as the notices present in *Vanguard.*

[7] In *Glaxo,* the district court was asked to approve a stipulation dismissing with prejudice a generic drug company's claim for a declaration that its product did not infringe certain patents. 325 F. Supp. 2d at 504. It declined to do so, finding that it lacked subject matter jurisdiction over the declaratory judgment action and could not enter a judgment that resolved the merits. However, after the assertion of counterclaims of non-infringement, the patentee apparently furnished a covenant not to sue and a stipulation of non-infringement to the generic company. *Id.* Under this Court's precedent, such a stipulation estopped the patentee from asserting the patents in the future, eliminated any genuine dispute between the parties and mooted any actual controversy. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995).

Because Novartis "started it," i.e., commenced litigation to prevent Teva from marketing a generic drug product that involved the same general technology covered by the Related Patents, Teva faced a "reasonable apprehension" that it would face infringement litigation based on those patents. Under this Court's precedent, Teva's declaratory judgment action presented an "actual controversy." The dismissal of that action must be vacated.

b. *Refusal to provide a covenant not to sue.* The pendency of Novartis' infringement suit on the '937 patent is not the only circumstance that supports the existence of a reasonable apprehension of suit on the Related Patents. Novartis has declined Teva's request for a covenant not to sue on the Related Patents. This Court has repeatedly noted that, while the refusal to give assurances that it will not enforce the patents alone is not conclusive, it is relevant. *Teva v. Pfizer,* 395 F.3d at 1333; *BP Chemicals Ltd. v. Union Carbide Corp.,* 4 F.3d 975, 980 (Fed. Cir. 1993); *see also Kos Pharms.,* 242 F. Supp. 2d at 317. Indeed, one of the principal purposes of the Declaratory Judgment Act was to permit parties to determine whether their conduct infringes a patent when the patentee refuses to give a straight answer to the question of infringement. As Judge Learned Hand observed half a century ago in a patent case:

> If a manufacturer fears that he will be charged to infringe, he can always inquire of the patentee, and if the answer is unsatisfactory, he can bring an action for a declaratory judgment. *The time has now passed when a patentee may sit by and refuse to show his hand.*

*Clair v. Kastar,* 148 F.2d 644, 646 (2d Cir. 1945) (emphasis added).

The Supreme Court has taken note of Judge Hand's observation that the Declaratory Judgment Act was designed in large measure to provide a remedy for parties otherwise unable to challenge "scarecrow" patents, i.e. patents on which the patentee does not bring suit but which deter prospective customers from doing business with the patentee's competitor. *See Cardinal Chem. Co. v. Morton Int'l, Inc.,* 508 U.S. 83, 95-96 (1993) (citing *Bresnick v. United States Vitamin Corp.,* 139 F.2d 239, 242 (2d Cir. 1943) (L. Hand, J.)). In *Cardinal,* the Supreme Court stated that "[m]erely the desire to avoid the threat of a 'scarecrow' patent ... may ... be sufficient to establish jurisdiction under the Declaratory Judgment Act." 508 U.S. at 96. When Congress amended the Hatch-Waxman Act to create a "civil action for patent certainty," it was simply implementing one of the original purposes of the Declaratory Judgment Act — to allow companies that have taken concrete steps to compete with patent owners to obtain a binding determination of the patentee's rights without incurring potentially massive liability for patent infringement.

Novartis can avoid any litigation over the Related Patents simply by a formal acknowledgment that Teva does not infringe them. Such an acknowledgment would moot the existing actual controversy over the Related Patents by giving rise to an estoppel against any future assertion of those patents against Teva with respect to the generic product described in Teva's ANDA. *Super Sack*, 57 F.3d at 1058. That Novartis may not be legally obliged to respond to Teva's demand for such an acknowledgment is beside the point. Its decision to reserve all of its rights under the Related Patents buttresses the reasonableness of Teva's apprehension that Novartis will attempt to enforce them.

c. *Novartis' consistent historic aggressiveness against Teva and other generic drug companies.* The reasonableness of Teva's apprehension of suit is further confirmed by the reality that Novartis has been aggressive in enforcing Orange Book patents against Teva and other generic drug companies. In the last five years alone, Novartis has commenced more than two dozen patent infringement actions against generic drug companies. (A210-211) Since 2004, Novartis has sued Teva on at least three occasions. (A214-215, 218-219) Famvir® is not the only drug as to which Novartis is not a "quiescent" patentee. Novartis' litigation history, like its refusal to

give a covenant not to sue, while not controlling, is relevant to the "reasonable apprehension" inquiry. *Teva v. Pfizer*, 395 F.3d at 1333.

Novartis' aggressiveness is neither unusual nor surprising. The amounts at stake in ANDA litigation are often very high. Novartis generates millions of dollars in sales of Famvir® *every month.* Delaying competition from generic companies for even a few months is worth a great deal to brand drug companies such as Novartis. Holding the Related Patents in reserve must be seen as part of a strategy to delay such generic competition, and thereby to deny the public the benefit of lower prescription drug prices for famciclovir products. Such a strategy plainly serves Novartis' economic interests. But Congress enacted the Hatch-Waxman Act and amended that Act to create a "civil action to obtain patent certainty" to accelerate the benefits that competition by generic companies brings to the public.

d. *Listing of Related Patents in the Orange Book.* Finally, Novartis itself chose to list the Related Patents in the Orange Book. To be sure, federal law required Novartis to list all patents that "claim[] the drug for which the [patentee] submitted the [new drug] application [i.e. famciclovir] or ... claim[] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21

U.S.C. §355(b)(1). But Novartis itself made the judgment that the Related Patents in particular could reasonably be asserted against any generic formulation of Famvir®.

This Court in *Teva v. Pfizer* concluded that the mere listing of a patent in the Orange Book did not "*without more*" establish a reasonable apprehension of suit. 395 F.3d at 1333. But the Court did not consider it irrelevant.[8] As explained above, there is much "more" presented here, including the critical fact that Novartis, unlike Pfizer, had already brought an infringement action against Teva arising out of Teva's ANDA application.

Consideration of the "totality of the circumstances," especially the pending litigation on the '937 patent, compels the conclusion that Teva faces a reasonable apprehension that Novartis will invoke the Related Patents to delay Teva's launch of a generic competitor to Famvir®. Since a justiciable controversy presently exists as to whether the Related Patents are valid and infringed by Teva's generic formulation, this Court should vacate the

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[8] At least one judge of this Court has found a patentee's public representation that a patent could reasonably be asserted against a generic formulation of a drug affirmatively supports the existence of a reasonable apprehension of suit. *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring). The *Teva v. Pfizer* majority declined to embrace Judge Gajarsa's conclusion that the Orange Book listing was sufficient to establish such a reasonable apprehension, but clearly did not consider the listing irrelevant.

dismissal for want of subject matter jurisdiction and remand the case for resolution of Teva's claim for declaratory relief on the merits.

### *C. Because of uncertainties concerning the constitutional status of the "reasonable apprehension" requirement in ANDA litigation, the test should be narrowly applied.*

The foregoing analysis has demonstrated that the instant case is distinguishable from *Teva v. Pfizer,* and that under the principles set forth in *Vanguard* and *Goodyear* the dismissal of Teva's complaint for declaratory relief in this case should be vacated. That result is particularly appropriate because of lingering uncertainty whether ANDA applicants should be required to demonstrate a "reasonable apprehension of suit" in order to bring a "civil action for patent certainty" under the Medicare Amendments to the Hatch-Waxman Act.

We recognize that the Court in *Teva v. Pfizer* ruled that proof of a reasonable apprehension of suit was constitutionally required, and that the enactment of the Medicare Amendments to the Hatch-Waxman Act did not alter that requirement.[9] We also recognize that the rule in this Circuit is that

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[9] If Article III requires proof of a "reasonable apprehension of suit," as the majority in *Teva v. Pfizer* concluded, Congress' intent in connection with the Medicare Amendments is entirely immaterial and the majority's attempt to discern that intent is perplexing. Even if Congress had more explicitly made provision to dispense with the reasonable apprehension requirement, the provision would be unconstitutional under the majority's view.

*(continued on next page)*

panel decisions are followed unless and until they are overturned by an *en banc* decision of this Court, *Newell Cos., Inc. v. Kenney Mfg. Co.,* 864 F.2d 757, 765 (Fed. Cir. 1988), or by the Supreme Court.

However, it is also true that of the five members of this Court who have written (or joined) opinions addressing whether ANDA applicants always need to establish a "reasonable apprehension" of suit to maintain a declaratory judgment action, three of them have answered in the negative. *See Teva v. Pfizer,* 395 F.3d at 1339-43 (Mayer, J. dissenting); *Teva Pharms. USA, Inc. v. Pfizer Inc.,* 405 F.3d 990, 997 (Fed. Cir. 2005) (Dyk, J., dissenting from denial of rehearing en banc); *id.* at 994 (Gajarsa, J., dissenting from denial of rehearing en banc). *See also Minnesota Mining & Mfg. Co. v. Barr Labs., Inc.,* 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring). While that does not detract from the binding character of *Teva v. Pfizer* under this Court's rules of practice, it does caution against *expanding* the ruling of that case where, as here, it is not necessary to do so.

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The majority's conclusion that Congress intended to preserve the reasonable apprehension test is equally perplexing. Nothing in the pre-amendment Hatch-Waxman Act precluded ANDA applicants from bringing declaratory judgment actions under traditional tests of justiciability if they were not sued within 45 days of their ANDA submissions. One wonders why Congress went to so much trouble to amend the Hatch-Waxman Act and 35 U.S.C. §271 to create a "civil action to obtain patent certainty" if it intended simply to preserve those tests.

Further reason for pause comes from the Supreme Court's decision to review this Court's ruling in *MedImmune.* In that case, this Court affirmed the dismissal of a declaratory judgment action brought by a patent licensee who challenged the validity of a licensed patent. The Court ruled that there was no subject matter jurisdiction because the licensee continued to pay royalties and otherwise comply with the license and therefore faced no reasonable apprehension of being sued for infringement by the patentee/licensor. 427 F.3d at 964-65. The grant of MedImmune's petition for certiorari places squarely before the Supreme Court whether the "reasonable apprehension" test is required to establish an "actual controversy."

With all due respect to the *Teva v. Pfizer* majority, Teva continues to believe that the reasonable apprehension test is not required by Article III. As the Supreme Court ruled in *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 241 (1937), Article III requires "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." The second part of this Court's traditional test — infringement, or concrete steps toward infringement, by the declaratory judgment plaintiff — ensures that this constitutional requirement is satisfied. The "reasonable

apprehension of suit" requirement, by contrast, reflects a policy judgment by this Court that "quiescent" patentees should not be put to the often considerable expense of defending a patent that they have given no signs of enforcing.

We submit that Congress made it clear that it intended federal courts to entertain "civil actions to obtain patent certainty" brought by ANDA applicants to the limits of Article III,[10] and did not express the view in the legislative history that the "reasonable apprehension" test was constitutionally required. Congress recognized that, in the end, whether the test was constitutionally required was a matter for the courts, not Congress, to decide.

This Court's determination that the reasonable apprehension test is constitutionally required has eliminated much of the utility of the "civil action to obtain patent certainty" created in the Medicare Amendments. That remedy for ANDA applicants comes into play only where the Orange Book patentee has declined, almost always for tactical reasons unrelated to the merits of the underlying patent dispute, to bring the infringement action

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[10] 35 U.S.C. §271(e)(5) provides that district courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by [an ANDA applicant] under [the Declaratory Judgment Act] for a declaratory judgment that such patent is invalid or not infringed."

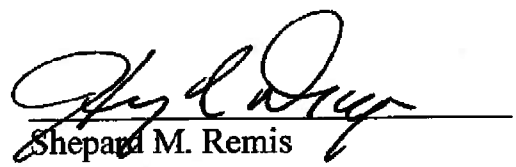
that Congress created in the original Hatch-Waxman Act. However, the very fact that the patentee has not brought suit, coupled with the ruling in *Teva v. Pfizer,* has effectively made the civil action for patent certainty unavailable in the only situations in which it could possibly matter, i.e. where the patentee has not sued the ANDA applicant within 45 days.

The instant case presents one of the few situations that is not governed by *Teva v. Pfizer* because in that case, unlike this one, the patentee had not sued the ANDA applicant on *any* of the patents listed in the Orange Book. Here, Novartis has "started it" with a suit on one of the listed patents. This Court's rulings in *Vanguard* and *Goodyear* provide a compelling basis for finding the existence of subject matter jurisdiction in this case without disturbing *Teva v. Pfizer.*

### *Conclusion*

For the reasons set forth in this brief, this Court should vacate the judgment of the District Court and remand the case for resolution of Teva's claims for declaratory relief.

Respectfully submitted,



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March 30, 2006

# ADDENDUM A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Civil No. 05-2881(JLL)

TEVA PHARMACEUTICALS, USA, INC.,

Plaintiff,

-vs-

NOVARTIS PHARMACEUTICALS CORP., ET AL,

Defendants.

TRANSCRIPT OF PROCEEDINGS

OPINION

December 12, 2005

Newark, New Jersey

B E F O R E:

THE HONORABLE JOSE L. LINARES,
UNITED STATES DISTRICT COURT JUDGE

Pursuant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above-entitled proceedings.

PHYLLIS T. LEWIS, C.S.R., C.R.R.
Official Court Reporter - United States District Court
P.O. Box 25588, Newark, New Jersey 07101

(732) 735-4522

THE COURT: This is in the matter of Teva Pharmaceuticals U.S.A., Inc. versus Novartis Pharmaceuticals Corp., et al., Civil Action No. 05-2881.

Presently before the Court is a motion by the defendants for the dismissal of the plaintiff's action pursuant to Rule of Civil Procedure 12(b)(1). This Court has considered the defendants' moving brief, the plaintiff's opposition brief and the defendants' reply brief and decides this matter without oral argument.

Having reviewed all of the briefs and the law cited therein, the Court grants the motion of the defendants for dismissal for the reasons that I will now state.

By way of background, the plaintiff in the present complaint seeks declaratory judgment of patent invalidity and noninfringement of four of defendants' assigned method patents related to the drug Famciclovir. The plaintiff was the first to file an ANDA with the Food & Drug Administration, which I will now refer to as the "FDA," seeking permission to manufacture and market Famciclovir.

As part of the plaintiff's filing and consistent with the Hatch-Waxman Act, the plaintiff provided a certification challenging the validity and infringement of the five patents. On April 8, 2005, within the statutory 45-day window, the defendants herein brought suit for infringement of the '937 patent. In that suit, which is

Civil Action No. 05-1887 presently pending before The Honorable Dennis Cavanaugh, defendant chose not to sue on the remaining four patents. Thereafter plaintiff brought this present separate action seeking the declaratory judgment of non infringement under the four remaining method patents pursuant to 28 USC Section 2201 for failure to meet the requirements of patentability under 35 USC Section 101, et seq.

In response to the plaintiff's action, the defendant filed this motion seeking dismissal of the action pursuant to Federal Rule of Civil Procedure 12(b)(1) claiming lack of subject matter jurisdiction. They assert that there is no reasonable apprehension of suit on the part of the plaintiff, and thus that there is no actual case or controversy that would give this Court subject matter jurisdiction. Defendants argue that the lack of an actual controversy stems from its choice not to sue for infringement of the four method patents that are the subject matter of the plaintiff's declaratory judgment action.

As defendants correctly indicated in its moving papers, the federal circuit has established a two-part test for cases like this, that is, cases of declaratory judgment involving patents. That two-part test is binding on this Court. Under this two-part test a party seeking jurisdiction must show that there is "Both (1) an explicit

threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment 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." See BP Chems. v. Union Carbine Corp. 4 F.3d 975, 978 (Fed. Cir. 1993) (citing Jervis B. Webb Co. v. Southern Sys., Inc., 742 F. 2d 1388, 1398-99 (Fed Cir. 1984).

In the case presently before this Court, the first prong is important in determining if there is in fact an actual controversy. The defendants argue that the first prong test is not met in this case in that the defendants' choice not to sue on the four method patents is within its rights under the Hatch-Waxman Act, the time for filing suit on the method patents has expired, there is no explicit threat to sue, and there is no reasonable apprehension of suit by the plaintiff.

Plaintiff, on the other hand, argues that the defendants admitted to the first prong in their motion to dismiss, and, in addition, they argue that the first prong is nevertheless met. They argue it is met through a combination of the suit filed by the defendants on the '937 patent, the defendants' history of suit against the plaintiff and other generic drug companies, and defendants' refusal to give plaintiff a covenant not to sue.

Notwithstanding plaintiff's assertion that the defendant has admitted to the first prong, a review of the defendants' briefing in this matter does not in fact indicate that. What is indicated in the second footnote of the defendants' brief is that, "Teva has satisfied the second prong of the federal circuit test by the filing of its ANDA."

Therefore, in order for this Court to determine whether it has jurisdiction, this Court must first determine, "Whether there is an actual controversy between the parties having an adverse legal interest. This depends on 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." See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (Fed. Cir. 2005) (rehearing denied en banc, 405 F.3d 990 (Fed. Cir. 2005) cert. denied, 2005, U.S. LEXIS 7632 (U.S. Oct. 11, 2005) (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)).

The first prong of the test, as previously indicated, is very important in determining if there is in fact an actual controversy. In this case there is no direct or express charge of pending suit on the four method patents. In light of this absence of an express charge of

pending suit, the Court then turns to the determination of whether in light of that totality of the circumstances the first prong has been met. See Teva v. Pfizer, 395 F.3d at 1333 (citations omitted). "This requirement of imminence reflects the Article III mandate that the injury be 'concrete' and actual or imminent, not just merely conjectural or hypothetical."

The facts of Teva v. Pfizer are very similar to the facts herein. Both cases involve Teva's filing of an ANDA and the failure of the patent holder to sue on one or more patents within the statutory 45-day period. Teva v. Pfizer, however, is distinct in that Teva filed a second ANDA and part of its claim for immediacy was based on a statutory 180-day exclusivity period for the first ANDA filer. This case is different in that here the immediacy aspect that existed in Teva v. Pfizer does not exist in this case and was not argued by the plaintiff. Therefore, this Court finds that the defendants did not admit to the first prong. It is also worth noting that the Teva suit was eventually dismissed for lack of jurisdiction on the ground that there was no reasonable apprehension that the patentee would file an infringement action. In that case plaintiff failed to demonstrate the existence of an actual controversy.

This Court entertained a similar issue in Glaxo Group v. Dr. Reddy's Laboratories, et al., 325 F. Supp. 2d

502 (D.N.J. 2004). In Glaxo Group Ltd. et al v. Dr. Reddy's Laboratories, et al, this Court stated that the fact that an ANDA had been filed and no infringement suit was filed was not dispositive, but instead that such actions must be considered in light of the "totality of the circumstances." See, inter alia, Id., 508 (citing Joint Explanatory Statement, Conference Agreement, for H.R.I., Provisions Related to Hatch-Waxman (November 21, 2003), (386). "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." In this case the plaintiff relies on a distinction that Novartis already filed suit, as compared with both Teva v. Pfizer and Dr. Reddy's v. Pfizer, Inc., 2003 U.S. District LEXIS, 24351 (D.N.J. July 8, 2003). In both of those cases, however, the court found for the patentee where the patentee had not filed suit against the infringer.

In this case both parties also cite to this Court's opinion in Glaxo v. Reddy, which was adjudicated prior to the Federal Circuit's ruling in Teva v. Pfizer, however further detail provided by the Fedearl Circuit in the Teva case are consistent with this Court's Glaxo v. Reddy finding. The court in that case analyzed the totality of the circumstances and objectively determined there was no

reasonable apprehension of suit, and therefore found no



actual case in controversy existed. Likewise in this case, this Court does not find that there is a reasonable apprehension of suit.

The plaintiff's arguments that the reasonable apprehension of suit could be based on the prior litigation history between the parties and that "Filing a lawsuit for patent infringement would be just another logical step in the defendants' quest to protect its technology." 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.

Therefore, under the totality of the circumstances, this Court finds there is no reasonable apprehension of suit. The plaintiff filed its ANDA seeking approval to manufacture and market Famciclovir. Plaintiff also informed the defendants of the filing and the potential challenges to five patents associated with the ANDA pertaining to defendants' patent.

The Hatch-Waxman Act affords the holder of the patent 45 days in which to bring suit. During the 45-day window, defendants however brought suit for infringement

only on the '937 patent. Defendant specifically did not bring suit on the remaining four patents, which, of course, is defendants' right under the Hatch-Waxman Act.

Furthermore, the facts are devoid of any further threats by defendants or any actions by the defendants that would give rise in this Court's opinion to a reasonable apprehension of any potential infringement action on the four remaining method patents. Therefore, this Court finds that under the totality of the circumstances, there is no reasonable apprehension of suit and thus no actual case in controversy.

The Court having made this finding concludes that the first prong established by the federal circuit in the two-part test for declaratory judgment cases has not been met. Thus, the defendants' motion to dismiss based on lack of subject matter jurisdiction is appropriate, and this Court will grant the defendants' motion.

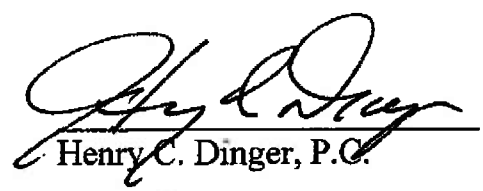
In light of the Court's finding, this Court need not make an analysis with regard to whether or not the second prong has or has not been satisfied since that issue is now moot.

An order embodying the Court's findings will issue.

* * * *

## CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of F.R.A.P. 32(a)(7)(C). This brief contains 7,956 words as calculated by the "Word Count" feature of Microsoft Word 2002, the word processing program used to create it.



Henry C. Dinger, P.C.

March 30, 2006

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30th day of March, 2006, two copies of Brief of Plaintiff-Appellant, Teva Pharmaceuticals USA, Inc. was served by Federal Express to:

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