No. 2007-1404

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff-Appellant,

v.

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, INC.,
and H. LUNDBECK A/S,
Defendants-Appellees.

On Appeal from the United States District Court for the Eastern District of Michigan in Case No. 3:07-CV-10737 Chief Judge Bernard A. Friedman

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES' COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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Dated: May 2, 2008

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies as follows:

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

Washington Legal Foundation

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 represented by me are:

None

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

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INTERESTS OF *AMICUS CURIAE*

The interests of amicus curiae Washington Legal Foundation ("WLF") are set forth in its motion for leave to file this brief. WLF agrees with Defendants-Appellees ("Forest Labs") that the panel decision conflicts with numerous prior decisions of this Court. WLF writes separately to emphasize the significant public importance of the issues raised by this petition.

REASONS FOR GRANTING THE PETITION

I. Rehearing Is Warranted Because Subject Matter Jurisdiction Is Lacking – In Light of Forest Labs' Unconditional Covenant Not To Sue, There Exists No Controversy Between Parties Having Adverse Legal Interests

Plaintiff-Appellant ("Caraco") seeks a declaratory judgment that it has not infringed a patent held by Forest Labs ("the '941 patent"). Although the Declaratory Judgment Act, 28 U.S.C. § 2201, permits parties to file suits in which (as here) the only relief sought is declaratory in nature, it did not (and could not) relax Article III's command that an actual case or controversy exist before federal courts may adjudicate a question. U.S. Const., Art. III, § 2. *See Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 272-73 (1941).[1]

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[1] The Act provides in relevant part:

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

The Act merely provides a different procedure for bringing an actual case or controversy before a federal court; it does not purport to expand federal court jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1941). The petition should be granted because the panel reached out to exercise jurisdiction over a case in which no actual case or controversy exists.

In *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), the Supreme Court recently reiterated the traditional formulation regarding the minimum prerequisites necessary to meet the case-or-controversy requirement:

> Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

MedImmune, 127 S. Ct. at 771. Caraco does not meet those prerequisites: there is *no* controversy (and certainly not a "substantial" one) between the parties regarding the '941 patent, they have no adverse legal interests, and any controversy lacks immediacy given the absence of any ongoing relationship between them. By providing Caraco with an unconditional covenant not to sue, Forest Labs eliminated any controversy and mooted all claims related to the '941 patent.

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28 U.S.C. § 2201(a). As this Court explained, § 2201(a)'s "actual controversy within its jurisdiction" language refers to the types of "Cases" and "Controversies" that are justiciable under Article III. *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1336 (Fed. Cir. 2007).

Prior to the *MedImmune* decision, this Court adhered to the "reasonable apprehension of suit" test, pursuant to which the case-or-controversy requirement barred suits by a party seeking a declaration that a patent was invalid or not infringed, unless the party had a reasonable apprehension that the patent holder would sue for infringement. *See, e.g., Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). *MedImmune* disapproved of the reasonable apprehension test, deeming it an unduly narrow interpretation of the case-or-controversy requirement. *MedImmune*, 127 S. Ct. at 774 n.11. But while *MedImmune* expanded this Court's prior understanding of Article III jurisdiction, it did so in a manner wholly unrelated to the facts of this case.

MedImmune addressed a situation in which the party seeking declaratory relief is himself preventing the complained-of injury from occurring. That is, only by complying with a demand from the defendant, a demand to which he objects, is the declaratory judgment plaintiff forestalling injury. The Supreme Court noted that under well-established case law, where the demand for compliance comes from the *government*, such a plaintiff need not refuse to comply with the demand – thereby exposing himself to sanction – before being permitted

to seek declaratory relief. *Id.* at 772.[2] The Court determined that the same rule should apply where the demand for compliance comes from a private party, at least where the threatened sanction for noncompliance is quite severe: "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III." *Id.* at 775. Thus, the plaintiff was permitted to seek a declaratory judgment that it was not infringing a patent at the same time that it was forestalling a potentially devastating infringement action by paying royalties to the patent holder. *Id.* at 777. The issue was no less a "substantial controversy" between the parties simply because the plaintiff was paying tribute to the patent holder under protest. *Id.*

Caraco's situation does not even remotely resemble the facts in *MedImmune*. Coraco is not making any payments to Forest Labs or taking any other actions at Forest Labs' behest. Caraco is refraining from marketing a generic form of Lexapro not because of any actions by Forest Labs but because FDA has not approved its ANDA. Nor has Forest Labs ever threatened to sue Caraco for

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[2] Thus, in *Steffel v. Thompson*, 415 U.S. 452 (1974), the Supreme Court "did not require the plaintiff to proceed to distribute handbills and risk actual prosecution before he could seek a declaratory judgment regarding the constitutionality of a state statute prohibiting such distribution." *Id.*

infringing the '941 patent; to the contrary, Forest Labs has provided Caraco with an unconditional covenant *not* to sue. In short, despite the panel's reliance on *MedImmune*, Slip Op. 14-18, nothing in the case provides support for the panel's conclusion that Caraco meets the case-or-controversy requirement.

Caraco, as the party claiming declaratory judgment jurisdiction, bears the burden of establishing that such jurisdiction existed at the time it filed suit *and at all times thereafter*. *Benitec Australia, Ltd v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1331 (2008). Once Forest Labs provided its unconditional covenant not to sue, Caraco could no longer meet that burden. *See id.* at 1345-47 (once patent holder promised not to sue defendant for patent infringement arising from activities occurring on or before the date of the district court's dismissal of the defendant's invalidity and noninfringement counterclaim, counterclaim was rendered moot; possibility of renewed suit years hence, if and when the defendant filed an NDA with FDA, did not create controversy of sufficient "immediacy and reality" to justify continued exercise of jurisdiction). Caraco is asking the federal courts to reach a legal determination that Forest Labs does not dispute: that Caraco's Paragraph IV certification did not violate Forest Labs's rights under the '941 patent. The federal courts lack Article III jurisdiction to issue such advisory opinions.

II. Rehearing Is Also Warranted Because Caraco Has Not Suffered Any Injury at the Hands of Forest Labs and Thus Lacks Standing

To establish its Article III standing, a party must at a minimum establish that it has suffered injury-in-fact directly traceable to the defendant's conduct. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998). Rehearing is warranted because Caraco has failed to establish any such injury. The panel held that Caraco has suffered injury-in-fact because Forest Labs' actions have delayed approval of its ANDA and thus its ability to market generic Lexapro. Slip. Op. 19-20. That injury is not directly traceable to Forest Labs. Rather, FDA approval of Caraco's ANDA is a multi-step process involving numerous variables.

The panel held that a judgment declaring the '941 patent not infringed would be an important step in the process of obtaining such approval. But even if the district court were to enter such a judgment, there is little reason to suppose that Caraco would gain FDA approval of its ANDA any more quickly than if no judgment were issued. First, such a judgment would do Caraco no good unless it *also* obtained a separate judgment that the '712 patent was invalid/not infringed; Caraco would need to win with respect to both patents in order to trigger Ivax's 180-day exclusivity period.[3] Second, it is up to FDA to

[3] *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). Caraco cannot get an ANDA until after expiration of the 180-day exclusivity period belonging to Ivax.

determine whether such a judgment is sufficient to start the clock on Ivax's 180-day exclusivity period. Moreover, there is no guarantee that FDA will ever approve Caraco's ANDA; although FDA has tentatively approved the ANDA, nothing prevents it from later determining, for example, that the ANDA is deficient for failing to meet the application requirements imposed by 21 U.S.C. § 355(j)(2)(A). Under those circumstances, there is no reasonable basis for attributing to Forest Labs responsibility for delays in approving Caraco's ANDA. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) ("The 'case or controversy' limitation of Article III . . . requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the individual action of some third party not before the court.").

Moreover, the Supreme Court holds that litigants may not use a declaratory judgment action to obtain piecemeal adjudication of issues that would not finally and conclusively resolve the underlying litigation. For example, in *Calderon v. Ashmus*, 523 U.S. 740 (1998), the Court held that prisoners on California's death row lacked standing to bring a declaratory judgment action against state officials, seeking a declaration that California failed to qualify for expedited federal habeas proceedings. The Court held that no case or controversy existed, because the prisoners could not show that they had been

injured by California's assertion that it *did* qualify for expedited federal proceedings.[4] The Court said that the real controversy between the parties was whether the prisoners were entitled to federal habeas relief, *i.e.*, an order setting aside their state court convictions. *Id*. at 746. The prisoners were simply "attempt[ing] to gain a litigation advantage by obtaining an advance ruling on an affirmative defense." *Id.* at 747. The action did not present a case/controversy because it "would not completely resolve" whether the prisoners were entitled to habeas relief but rather "would simply carve out one issue in a dispute for separate adjudication." *Id.* at 749. The Court explained that "the traditional scope of declaratory judgment actions" encompasses only those suits whose resolution "completely resolve[] a concrete controversy susceptible to conclusive determination." *Id*.

MedImmune cited *Calderon* with approval and reaffirmed the principle that the Declaratory Judgment Act does not authorize suits designed to resolve one issue within a larger controversy. It cited *Calderon* for the proposition that "a litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying

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[4] A 1996 federal statute permits States to qualify for expedited federal habeas corpus proceedings for capital prisoners (thereby eliminating often substantial delays in carrying out sentences), but only if the States can demonstrate they have implemented a system designed to ensure that murder defendants are adequately represented by counsel in state court. *See id.* at 742-43.

controversy." *MedImmune*, 127 S. Ct. at 771 n.7. *MedImmune* and *Calderon* make clear that Caraco may not use a declaratory judgment action against Forest Labs to gain an advantage in its underlying controversy with FDA.

The panel sought to bolster its ruling by citing a Senator's 2003 statement with respect to 21 U.S.C. § 355(j)(5)(C), a statute adopted some years earlier. Slip Op. at 8-9. That provision grants a Paragraph IV ANDA filer the right to file an action seeking a declaration of patent invalidity/noninfringement if the patentee does not file an infringement action within 45 days of the Paragraph IV filing. But Congress does not and cannot decree the existence of Article III jurisdiction where it does not otherwise exist; a party authorized to file suit under § 355(j)(5)(C) must independently establish its standing to sue.

Moreover, procedural rights of the sort created by the statute are not the sort of statutory rights whose violation can give rise to the injury-in-fact necessary to establish standing. Thus, for example, *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), held that the plaintiffs lacked standing to challenge alleged violations of the Endangered Species Act even though the law contains a citizen-suit provision that authorizes private citizens to sue to enjoin violations of the Act. The Court explained that even when Congress creates a right of action authorizing private individuals to file suit, the plaintiffs nonetheless may not invoke federal court jurisdiction unless they can establish standing – which

requires, among other things, a showing of injury-in-fact. *Id.* at 576. The Court held that where, as in that case, the plaintiffs could not demonstrate injury-in-fact, the federal courts lack Article III jurisdiction to hear the case; Congress's creation of a private right of action is not sufficient. *Id.*

Congress is, of course, entitled to adopt statutes creating new substantive rights. When it does so, an infringement of those rights can give rise to injury-in-fact that can form the basis for a plaintiffs' standing.[5] But as *Lujan* explained, "Statutory broadening of the categories of injury that may be alleged in support of standing is a different matter from abandoning" traditional standing requirements, such as that the plaintiff suffer some actual injury. *Id.* at 578.[6]

CONCLUSION

WLF respectfully requests that the combined petition be granted.

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[5] An example of a congressional statute that creates a new substantive right is 35 U.S.C. § 271(e)(2)(A). Adopted as part of the Hatch-Waxman Act in 1984, that statute declares that the filing of a Paragraph IV certification injures the patent holder by infringing her property rights in the patent.

[6] Moreover, Congress made clear that it did not authorize filers of Paragraph IV certifications to bring declaratory judgment actions without regard to their Article III standing. *See* 35 U.S.C. § 271(e)(5) (limiting federal court subject matter jurisdiction over such declaratory judgment actions to those cases in which an assertion of jurisdiction is "consistent with the Constitution.").

Respectfully submitted,

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Dated: May 2, 2008

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I HEREBY CERTIFY that on this 2nd day of May, 2008, two copies of the foregoing brief of *amicus curiae* Washington Legal Foundation were deposited in the U.S. Mail, first-class postage prepaid, addressed as follows:

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