No. 2007-1404

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff-Appellant,

v.

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

On Appeal from the United States District Court
for the Eastern District of Michigan, No. 3:07-CV-10737 (Friedman, J.)

BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF REHEARING AND/OR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Amici Curiae Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Industry Organization ("BIO") certifies the following:

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

   Pharmaceutical Research and Manufacturers of America

   Biotechnology Industry Organization

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:

   PhRMA is a membership organization, and a list of its members, international affiliates, and associate members is set forth below:

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

None for PhRMA.

None for BIO.

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

PhRMA and BIO did not appear in the trial court. Before this Court, PhRMA and BIO are represented by:

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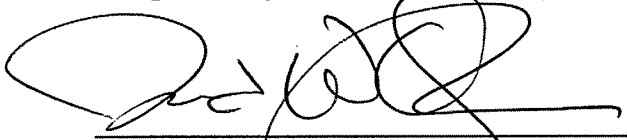

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Counsel for Pharmaceutical Research and Manufacturers of America and Biotechnology Industry Organization as Amici Curiae

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STATEMENT OF INTEREST

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies which last year spent $44.5 billion on the discovery and development of new drugs. The Biotechnology Industry Organization ("BIO") is the largest trade association representing more than 1,100 businesses and research institutions engaged in the research and development of biotechnology products, including new drugs and biologics. PhRMA and BIO submit this brief in support of rehearing and/or rehearing en banc because the panel's erroneous decision upsets basic principles of Article III standing and declaratory judgment law, and disrupts the careful balance that Congress established in the Hatch-Waxman Act, thereby undermining the incentives that Congress provided to encourage the discovery and development of new drugs.[1]

INTRODUCTION

This case presents a novel and important question under the Hatch-Waxman Act with ramifications far beyond it: whether an Article III case or controversy exists, and a declaratory judgment action may lie, notwithstanding the fact that a party has issued an irrevocable covenant not to sue. In holding that jurisdiction extends to such an action—despite the fact that there is otherwise no possibility of

[1] None of the parties in this action is a member of either PhRMA or BIO.

current or future litigation between the parties on the ’941 patent—the panel’s opinion misapprehends Article III standing and declaratory judgment law. *See* Part I *infra*. In addition, while the panel appeared to perceive a problem with Hatch-Waxman’s incentives, the panel’s opinion in fact disrupts the delicate balance set up by Congress. *See* Part II *infra*. Finally, the panel’s decision interferes with a basic tenet of patent law: that a patentee should not be forced to litigate. *See* Part III *infra*. This Court should therefore grant rehearing and/or rehearing en banc.

ARGUMENT

I. THE PANEL’S OPINION IS INCONSISTENT WITH BASIC PRINCIPLES OF ARTICLE III STANDING AND DECLARATORY JUDGMENT LAW

The panel’s decision contravenes basic principles of both Article III standing and declaratory judgment law. The panel not only found Article III standing where there was no chance of present or future litigation between the parties on the ’941 patent, *see* Part I.A *infra*, but it also failed to consider an independent requirement of declaratory judgment law, namely, whether there is a live cause of action underlying the request for declaratory relief, *see* Part I.B *infra*.

A. There Is No Article III Case Or Controversy

The Supreme Court has made clear that, in order for Article III jurisdiction to lie in a declaratory judgment action, there must be a “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v.*

Genentech, Inc., 127 S. Ct. 764, 771 (2007) (internal quotations omitted). Here, however, this test cannot be met, as Forest granted Caraco an irrevocable covenant not to sue on the '941 patent. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, No. 2007-1404, 2008 WL 850330, at *7 (Fed. Cir. Apr. 1, 2008). As a result, there is no risk of any litigation by Forest on that patent—either today or in the future—thereby negating any Article III case or controversy. *See Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1347-1348 (Fed. Cir. 2007) (finding no jurisdiction where declaratory defendant promised not to sue and noting that there "was no controversy between the parties concerning infringement").

Although the panel relied on the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), that case presented a starkly different situation. In *MedImmune*, the party seeking to bring the declaratory judgment could have faced "the threat of treble damages and loss of 80 percent of [its] business" if it ceased paying royalties. *Id.* at 775 n.12. The Court held that where a party is acting under "coercion," and seeks a declaration of its rights in order to put an end to such coercion, there is a justiciable controversy under Article III and the Declaratory Judgment Act. *Id.* at 773 & n.9; *see also id*. at 775 n.12 (referring to "[t]he coercion principle upon which we rely"). In other words, the Court held that a party should not be forced to take a significant legal risk—and effectively "bet the farm," *id.* at 775—in order to invoke the jurisdiction of the

federal courts. "The dilemma posed by that coercion … is a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Id.* at 773 (internal quotations omitted). In the current case, by contrast, there is absolutely no "coercion" present.[2] Indeed, even the possibility of *future* coercion has been removed, as Forest has agreed never to sue Caraco on the '941 patent.[3]

The panel nonetheless found Article III standing because Caraco cannot presently bring its drugs to market. *Caraco*, 2008 WL 850330, at *14. Yet this result is due to the threat of FDA action and the operation of the statute. Under the statute, the FDA may not approve later-filing generics (such as Caraco) until after the first filer's period of exclusivity has run. *See* 21 U.S.C. § 355(j)(5)(B)(iv). If Caraco nonetheless brought its drugs to market tomorrow, without first receiving FDA approval, it might face an enforcement action by the FDA. *See id.* §§ 331(d), 355(a). Forest, however, would still be unable to sue Caraco for infringement of the '941 patent (in light of the covenant not to sue). Nor would Forest be able to sue Caraco for violating FDA requirements, as there is no such private right of action. *See id*. § 337(a); *see also, e.g., Mylan Pharms., Inc. v. Thompson*, 268 F.3d

[2] Nor can the listing of the '941 patent in the Orange Book be deemed a coercive act, as listing is mandated by statute. *See* 21 U.S.C. § 355(b)(1), (c)(2).

[3] This Court's decision in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed. Cir. 2007), is distinguishable for similar reasons. In that case, the generic faced a very real threat of litigation, *see, e.g., id.* at 1341, and was therefore subject to coercion that is wholly absent here.

1323, 1332 (Fed. Cir. 2001) (noting "long line of cases precluding private rights of action under the [Federal Food, Drug, and Cosmetic Act]"). Caraco's only live legal dispute, then, is with the FDA—not Forest—and any "coercion" felt by Caraco is due to the threat of FDA enforcement under the statute—a potential action not within Forest's control.

B. The Declaratory Judgment Act Does Not Provide A Cause Of Action And There Is No Justiciable Cause Of Action Here

Apart from the Article III case-or-controversy requirement, the panel overlooked the equally important question of whether Caraco has a *cause of action* against Forest in the present case.

It is well settled that the Declaratory Judgment Act, 28 U.S.C. § 2201, is a "procedural only" remedy, *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937); it does not create new substantive rights, but merely permits a party who would otherwise be the defendant in a coercive action to initiate suit. *See Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-672 (1950). Accordingly, this Court has stated that, "[w]ithout an underlying legal cause of action, any adverse economic interest that the declaratory plaintiff may have … is not a legally cognizable interest sufficient to confer declaratory judgment jurisdiction." *Benitec Australia, Ltd.*, 495 F.3d at 1344 (internal quotations omitted); *see also Mylan Pharms.*, 268 F.3d at 1331 (noting that a court must "determin[e] which federal law is the basis for the declaratory plaintiff's cause of action").

Forest, however, no longer has a cause of action against Caraco, as Forest has executed an irrevocable covenant not to sue. *Caraco*, 2008 WL 850330, at *7, 13; *see Microchip Tech. Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006) (finding no jurisdiction for declaratory judgment action where "Microchip has not identified a single legal claim that it believes Chamberlain could have brought against it in the absence of this declaratory judgment action"). Indeed, if Caraco is permitted to bring a declaratory judgment action on the '941 patent, notwithstanding the lack of a cause of action, it is difficult to fathom how such a case would proceed, or the issues that the district court would resolve.[4] Nor has Congress created an express or implied right of action for the right Caraco seeks to vindicate in this case: to enforce the provisions of the Federal Food, Drug, and Cosmetic Act through a private party such as Forest. *Cf. Mylan Pharms.*, 268 F.3d at 1332 (noting "long line of cases precluding private rights of action under the FFDCA"). Thus, declaratory judgment jurisdiction cannot lie.

II. THE COURT SHOULD NOT HAVE INTERVENED TO FAVOR ONE OF THE COMPETING GOALS OF HATCH-WAXMAN

The panel seemed to believe that it needed to find jurisdiction in order to effect what it saw as the objectives of the Act. It was wrong to do so.

[4] Forest's covenant not to sue precludes it from bringing an affirmative infringement action against Caraco. If Forest is nonetheless forced to litigate the claim in a declaratory judgment action, a unique puzzle is created, as it is unclear whether Forest must (or may) assert infringement in defense of Caraco's claim.

A. The Panel's Opinion Interferes With Congress's Delicate Balance

The Hatch-Waxman Act is a complicated, finely calibrated statute that governs the approval of new and generic drugs by the FDA. *See generally Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-1371 (Fed. Cir. 2002) (describing Hatch-Waxman scheme). The Act strikes a delicate balance between numerous competing goals, including: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Id.* at 1371; *see also Caraco*, 2008 WL 850330, at *11 (Act represents a "carefully crafted dialectic balance"). The Act also establishes unique incentives for the first firm to file a Paragraph IV ANDA,[5] by granting the first filer a 180-day exclusive right to market a generic version of the drug alongside the brand-name firm. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

The panel seemed to believe that permitting a declaratory action here was necessary to give effect to one of these competing goals, namely, bringing generic drugs to market. But by giving undue weight to this one goal, the panel's opinion undermines Congress's carefully calibrated scheme, thereby disrupting other objectives of the statute and potentially having a detrimental impact on the pharmaceutical market as a whole. The panel's opinion will disrupt the incentives

[5] By filing a Paragraph IV ANDA, the generic manufacturer alleges that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

for first filers (by permitting, for example, subsequent filers like Caraco to artificially trigger the first filer's 180-day exclusivity, and before the first filer can use it), and will dilute the incentives for firms to discover and develop new drugs (as the decision will invariably subject branded companies to increased litigation). The panel should not have interfered with the delicate balance struck by Congress. *See Eldred v. Ashcroft*, 537 U.S. 186, 205 n.10 (2003) (noting, in copyright case, "it is not our role to alter the delicate balance Congress has labored to achieve" (internal quotations omitted)); *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) ("The underlying determination about the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress to make.").

In fact, since the passage of the Act in 1984, Congress has amended the Act to fine-tune the Act's incentives. In 2003, and partly in response to concerns about the perceived "approval bottleneck" that delayed the entry of later-filing generic firms to the market, Congress made several discrete amendments to the main provision at issue in this case. Congress replaced the "court-judgment trigger," *see* 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000), with a complex, interlocking set of provisions requiring the "forfeiture" of the first filer's 180-day exclusivity period in carefully defined circumstances, 21 U.S.C. § 355(j)(5)(D)(i)(I)-(VI). Though Congress provided that the "failure to market" forfeiture event may be triggered by

a number of discrete events, *id*. § 355(j)(5)(D)(i)(I)(bb)(AA)-(CC), it did not include a "covenant not to sue" in this list. Although these amendments do not apply to this case,[6] the scalpel-like precision with which Congress amended the Act reflects Congress's conscious effort to uphold the balance between the Act's incentives to spur innovation, on the one hand, and to encourage generic drugs to come to market, on the other. The panel's opinion disrupts that delicate balance.

B. The Panel Was Incorrect To Perceive A Problem

The panel was also wrong to attempt to fix a nonexistent problem, as the ordinary operation of the statute already provides a solution.

First, under the normal operation of the statute, generic versions of the Forest product will likely come to market in a few years (*i.e.*, in 2012). At that time, the '712 patent will expire, and the first filer (Ivax) will be able to market its generic drug. *Caraco*, 2008 WL 850330, at *6. And there is every reason to believe that Ivax will do so. *See id.* at *12 n.14. Thus, the various goals of the Act—inducing innovation, permitting generics to come to market in a structured way, and providing incentives to first filers—will be effected in the present case.

Second, under the statutory scheme set up by Congress, any harm to Caraco is simply a consequence of the fact that Hatch-Waxman places first filers in an

[6] Congress did not make the 2003 amendments retroactive where, as here, a Paragraph IV ANDA was filed for the drug prior to the December 8, 2003 enactment of the amendments. *See Caraco*, 2008 WL 850330, at *3 n.2.

advantageous position vis-à-vis subsequent filers. The Act grants 180 days of exclusivity as a benefit for bearing the costs of filing the first ANDA, such that later filers must wait in line behind the first. Having failed to file first, Caraco is now waiting in a statutorily-established queue—and should not now be heard to complain about consequences caused by the statute and its own choice.

III. THE PANEL'S DECISION INTERFERES WITH A PATENTEE'S RIGHT NOT TO LITIGATE

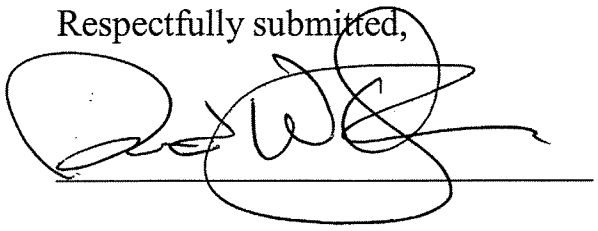
Finally, the panel's decision disrupts a basic tenet of patent law: that a patent owner should not be forced to litigate and has a "right [] either not to sue or not to be provoked into suit." *Shell Oil Co. v. Amoco Corp*., 970 F.2d 885, 889 (Fed. Cir. 1992). This Court has cautioned that declaratory judgment actions "should not be used to force unwanted litigation on quiescent patent owners." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 812 (Fed. Cir. 1996) (internal quotations omitted); *see also* Borchard, *Declaratory Judgments* 807 (2d ed. 1941) (expressing "fear that patentees might be harassed by prospective infringers and be obliged continually to defend their patents"). By finding jurisdiction notwithstanding Forest's covenant not to sue, the panel's opinion interferes with Forest's fundamental right not to be coerced into litigating its patents.

CONCLUSION

This Court should grant rehearing and/or rehearing en banc.

May 5, 2008

Respectfully submitted,



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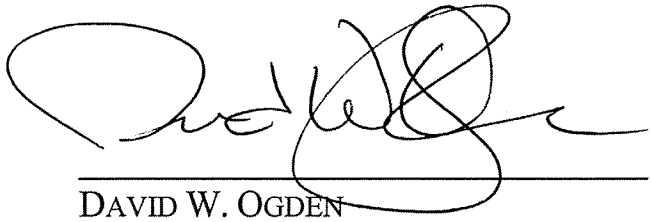

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Dated: May 5, 2008

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