No. 05-608

**IN THE**
**Supreme Court of the United States**

MEDIMMUNE, INC., PETITIONER,

v.

GENENTECH, INC., ET AL., RESPONDENTS.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT*

# AMICUS BRIEF FOR PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA SUPPORTING RESPONDENTS

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## INTEREST OF AMICUS [1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. Member companies are in the business of developing new drugs – a complex process involving huge expenditures of time and money. Collectively, PhRMA members are responsible for a huge portion of the innovative medicines approved for use in the United States in the past several decades. In 2005, PhRMA members invested an estimated $39.4 billion toward the discovery and development of new medicines.

Pharmaceutical companies spend many years working to develop each new drug that appears on the market, as well as many that will never earn approval. The process typically begins with creating a new compound or screening hundreds of thousands of existing compounds. The most promising compounds are then modified to optimize their properties, thus producing a candidate drug. Selected compounds are then tested in the lab and in animals to determine whether they might effectively and safely treat a disease. This is followed by clinical trials in normal human volunteers and a series of studies in a relatively small number of patients. The next stage of development is a series of large clinical trials testing the effectiveness as well as the safety of a drug in patients. These clinical trials, typically taking six to eight years, precede the process of seeking approval from the Food and Drug Administration ("FDA"). Altogether, the entire drug development process might last upwards of fifteen years.

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[1] The parties have consented to the filing of this brief. No party authored the brief in whole or in part or contributed monetarily to its preparation or submission. A list of PhRMA's members, and other information about PhRMA, may be found at www.phrma.org.

Practicing in an industry where research and development are expensive and competition is fierce, PhRMA's members depend on strong patent protection to recoup the investments necessary to develop new medicines. The "reasonable apprehension" test applied by the Federal Circuit in this case provides important patent protection for PhRMA's members in connection with applications for new drug approvals by generic manufacturers. PhRMA files this brief to caution against disavowing the "reasonable apprehension" test in this case.

## ARGUMENT

### I. THE COURT NEED NOT DECIDE WHETHER ARTICLE III MANDATES THE "REASONABLE APPREHENSION" TEST IN ALL SETTINGS.

The Court of Appeals for the Federal Circuit upheld the dismissal of this action on the ground that Petitioner, as a licensee in good standing, had no "reasonable apprehension" of being sued for patent infringement by Respondents. In the court's view, a potential infringer must have a "reasonable apprehension" of being sued for infringement to present a case or controversy sufficiently real and immediate to support the exercise of Article III jurisdiction. Pet. App. 4a-9a.

Petitioner and its *amici* urge the Court to disapprove the Federal Circuit's "reasonable apprehension" test categorically as more restrictive than Article III requires and therefore not a proper basis for dismissal. Pet. Br. 22-28; US Br. 14-19; GPhA Br. 10-13. But the test cannot be considered apart from the setting in which it is applied, and the Court should not here prejudge the test's application in other settings. *Cf. Johnson* v. *United States*, 333 U.S. 46, 56 (1948) (Frankfurter, J., joined by Jackson & Burton, JJ., dissenting in part) ("One cannot be unmindful that 'the radiating potencies of a decision may go beyond the actual holding.'") (citation omitted).

The Court granted review here not to decide whether Article III mandates the "reasonable apprehension" test, but to decide whether Article III "require[s] a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed." That question goes to the rights and duties of licensees and licensors, a field shaped by three centuries of common law. Resp. Br. 29-30. GPhA, as *amicus*, urges the Court to review the application of the "reasonable apprehension" test in the Hatch-Waxman setting. *See* GPhA Br. 2, 4, 8-9. But the application of the test in that setting implicates issues different from those implicated here. Whether to consider the test's application in that setting is the subject of a pending petition for review in *Apotex, Inc.* v. *Pfizer Inc.*, No. 05-1006. The Court should not rule in this case on the validity of the test in that setting.

Although the answer to the question on which the Court granted review has potentially broad implications, the question itself is narrow, and the answer should be no broader than the question. *See, e.g.*, *Greater New Orleans Broad. Ass'n, Inc.* v. *United States*, 527 U.S. 173, 184 (1999). As discussed by Respondents and their *amici*, the Federal Circuit's judgment can be affirmed without resort to the "reasonable apprehension" test. *Cf. Chevron U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984) ("[T]his Court reviews judgments, not opinions."). The Court could even affirm the judgment below without reaching the Article III issue. *See* Resp. Br. 35-45; ABA Br. 17-19. Because the "reasonable apprehension" test may have utility in other contexts, the Court should avoid a decision here that might bear on the application of the test in other contexts.

## II. ALTERNATIVELY, ARTICLE III REQUIRES THE "REASONABLE APPREHENSION" TEST.

Article III limits the jurisdiction of federal courts to actual "cases" or "controversies." For an actual case or con-

troversy to exist, Article III requires a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co.* v. *Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Congress cannot expand the jurisdiction of the federal courts beyond the limits set by Article III and therefore cannot confer jurisdiction where an actual case or controversy does not exist. *See*, *e.g.*, *Verlinden B.V.* v. *Cent. Bank of Nig.*, 461 U.S. 480, 491 (1983).

Accordingly, from the earliest days of the Declaratory Judgment Act, the Court has recognized that a declaratory judgment action may be brought only in "a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding." *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 241 (1937). Lower courts have long employed the "reasonable apprehension" test in patent cases to implement Article III's requirements of concreteness and immediacy. *See*, *e.g.*, *Japan Gas Lighter Ass'n* v. *Ronson Corp.*, 257 F. Supp. 219, 237 (D.N.J. 1966). The test has been applied in trademark and copyright cases as well. *See, e.g.*, *Starter Corp.* v. *Converse, Inc.*, 84 F.3d 592 (1996) (2d Cir. 1996) (trademark); *United Christian Scientists* v. *Christian Sci. Bd. of Dirs.*, 829 F.2d 1152 (D.C. Cir. 1987) (copyright). The "reasonable apprehension" test is not simply a prudential rule but an aspect of Article III. *See*, *e.g.*, *Fina Oil & Chem. Co.* v. *Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997) (stating that the reasonable apprehension test "respects the constitutional requirement of an actual controversy"); *Interdynamics, Inc.* v. *Firma Wolf*, 698 F.2d 157, 166 (3d Cir. 1982) (stating that the reasonable apprehension standard is "identical to the constitutional requirement of 'cases' and 'controversies'").

A patent license permits the licensee to practice a patented invention in return for making royalty payments to the licensor. As long as the licensee pays the royalties and

otherwise satisfies the terms of the license, the licensee may practice the invention, and the licensor may not sue the licensee for infringement. *See*, *e.g.*, *Ortho Pharm. Corp.* v. *Genetics Inst.*, 52 F.3d 1026, 1031 (Fed. Cir. 1995). By definition, such a licensee cannot have a "reasonable apprehension" of an infringement suit by the licensor. Any claim by such a licensee that the patent is invalid is necessarily "conjectural or hypothetical," *Steel Co.* v. *Citizens for a Better Env't*, 523 U.S. 83, 101 (1998), and therefore does not satisfy Article III's case-or-controversy requirement. (To be sure, if the licensor sues the licensee for infringement, the licensee may seek a declaration that the patent is invalid. *See Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83 (1993). That, however, is because the suit brought by the licensor makes the issue of validity immediate and real.)

GPhA suggests that the "reasonable apprehension" test would bar an infringer from seeking a declaration of invalidity where the patentee has elected to sue infringers separately and has not yet sued the infringer. GPhA Br. 13. Whether such an infringer has a "reasonable apprehension" of suit sufficient to vest a federal court with subject matter jurisdiction will depend on the particular facts of the case. *See, e.g.*, *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004) (noting that the existence of subject matter jurisdiction under the "reasonable apprehension" test depends on the "totality of the circumstances"). Standing alone, however, a patentee's failure to sue a putative infringer cannot give rise to a "case or controversy," even if that patentee has sued other infringers.

GPhA is likewise mistaken in its criticism of the Federal Circuit's rule in *Teva Pharmaceuticals USA, Inc.* v. *Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005). In that case, a patentee declined to exercise its statutory right to sue a potential infringer for infringement because the patentee did "not wish to expose the patent to the possibility of a noninfringement or invalidity determination." *Id.* at 1333.

The Federal Circuit affirmed the lower court's dismissal of the potential infringer's declaratory judgment action as lacking the immediacy required by Article III.

This case obviously does not present the same issues. In *Teva*, the patentee could have sued the alleged infringer. Here, Respondents cannot sue Petitioner because they have granted Petitioner the right to practice the patented invention in return royalty payments. As long as Petitioner makes those payments and otherwise complies with the license's terms, it faces no threat of an enforcement action, imminent or otherwise, and there is no case or controversy of sufficient concreteness and immediacy to justify the intervention of the federal courts.

In any event, the Court has long recognized that, in order to bring a declaratory judgment action, a party must face a real prospect of suffering adverse consequences in the absence of a binding judicial determination on a disputed matter. This rule applies even where a party contemplates action that might violate a criminal statute: To seek prospective relief, a party must show a "genuine threat of enforcement." *See Steffel* v. *Thompson*, 415 U.S. 452, 475 (1974). Thus, for example, in *Boyle* v. *Landry*, 401 U.S. 77, 81 (1971), the Court refused to issue a declaratory judgment because there was no "specific threat by any officer or official . . . to arrest or prosecute" the plaintiffs; resolution of the issue therefore would have constituted impermissible "speculation about the future." *See also* 10B Charles Alan Wright, *et al.*, *Federal Practice and Procedure* § 2757, at 477-84 (3d ed. 1998) ("[C]ourts have declined to hear cases seeking a declaratory judgment on the constitutionality of a particular statute or ordinance when plaintiff has not shown that there is any immediate threat that the statute will be enforced against him."). Like parties who may not challenge state laws absent a threat of enforcement, patent infringers are precluded from seeking declaratory judgments where the patentees have disavowed any intention to sue.

In light of these principles, the Federal Circuit's "concern for protecting 'quiescent' patentees," GPhA Br. 16, is legitimate. Contrary to GPhA's suggestion, *id.* at 17, the Federal Circuit in *Hunter Douglas, Inc.* v. *Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998), decided that it lacked jurisdiction not because the "reasonable apprehension" test protects quiescent patent holders, but because to have decided the question in that case would have been to "render[ ] a forbidden advisory opinion," *id.* at 1326 (internal quotations omitted). Given the Court's repeated admonitions that a party must face a genuine threat of enforcement before seeking a declaratory judgment, it is hardly surprising that potential infringers of a quiescent patentee may not hale the patentee into court *willy-nilly*.

Federal courts have long required more than a hypothetical possibility of an infringement suit to ground declaratory judgment jurisdiction. As the Court has stated:

> The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree . . . 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.

*Md. Cas. Co.*, 312 U.S. at 273.[2] As stated by one District Court:

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[2] *See also EMC Corp.* v. *Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996) ("This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be

(continued…)

> In the absence of strong objective evidence sufficient to indicate intent to initiate an enforcement action, the mere listing of multiple patents does not create declaratory judgment jurisdiction . . . [where the generic manufacturer] has not alleged objective words or actions by [the innovator] that demonstrate an intent to enforce its patent rights . . . either through explicit threats or indirect threats or actions that place the declaratory plaintiff in reasonable apprehension of suit.

*Dr. Reddy's Labs., Ltd.* v. *Pfizer Inc.*, No. 03-CV-726, 2003 WL 21638254, at *5-6 (D.N.J. July 8, 2003). Instructing federal courts to assume jurisdiction over cases in which a patentee has taken no specific actions against an infringer or potential infringer would violate these long-standing principles, and would have the effect of courts issuing advisory opinions in violation of Article III's jurisdictional limitations.

For these reasons, there is no basis in law for asserting that the reasonable apprehension test is *not* constitutionally required or that the test, when applied appropriately, is not aligned with the requirements of Article III. Instead, the correct understanding of the law is that courts are required to assess, on a case-by-case basis, whether there are specific facts in the record to satisfy the constitutional requirement of an actual case or controversy, in-

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deemed a controversy."); *Phillips Plastics Corp.* v. *Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("[T]o create an actual controversy . . . [t]here must be action by the patent holder sufficient to create an objectively reasonable apprehension that suit will be brought against the declaratory plaintiff."); *BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("[M]ore is required than the existence of an adversely held patent.").

cluding whether there is a reasonable apprehension of suit.

Finally, GPhA urges that the "equalizing principles" that the Federal Circuit reasoned underlie the Declaratory Judgment Act are not recognized by this Court. GPhA Br. 18-20. But the policies relied on by the Federal Circuit in implementing the Declaratory Judgment Act's requirements here are entirely consistent with both the Declaratory Judgment Act and this Court's cases.

As the Federal Circuit has explained, the purpose of the Declaratory Judgment Act is to

> enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side. It accommodates the practical situation wherein the interests of one side to the dispute may be served by delay in taking legal action.

*BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 977 (Fed. Cir. 1993).

In this case, Respondents hold no procedural advantage over Petitioner. On the contrary, Respondents are barred from bringing an infringement action against Petitioner by the license agreement. Thus, under the Federal Circuit's rule, *neither* party may presently bring an action against the other. Under the rule urged by Petitioner, it would have a right to institute an action against Respondents, while Respondents could not sue it for infringement. The Declaratory Judgment Act was designed to prevent just such inequality.

*Maryland Casualty*, 312 U.S. 270, is not to the contrary. In that case, an insurer sought a declaratory judgment against its insured and a third party stating that its policy did not cover the third party's claim against the insured. It was beyond dispute that the insurer's claim a-

gainst the insured was of sufficient immediacy to present an actual controversy under Article III; the insurer's suit against the insured was the mirror-image of the affirmative suit that the insured could have brought against it.

The Court also concluded that the insurer's claim against the third party could proceed, even though the third party could not sue the insurer until after the insured failed to satisfy a judgment in the insurer's favor. The Court's conclusion, however, was based on a fact not present in this case – the possibility of inconsistent judgments in the federal-court proceeding between the insurer and the insured and a later state-court proceeding between the insured and the third party. *See id.* at 274. Thus, *Maryland Casualty* does not undermine the principles of equality and fairness that underlie the Declaratory Judgment Act and antithetical to the role proposed by Petitioner in this case.

## III. CONGRESS AFFIRMED THE "REASONABLE APPREHENSION" TEST WHEN IT AMENDED HATCH-WAXMAN IN 2003.

Petitioner and its *amici* assert that Congress enacted the Declaratory Judgment Act, in part, to enable a party to seek a judicial determination of non-infringement or invalidity before undertaking activity that could subject the party to potentially ruinous liability. *See* Pet. Br. 29-33; U.S. Br. 9, 19; GPhA Br. 5-7. This general proposition, to the extent that it is accurate, is irrelevant here. Whatever prospective declaratory relief Congress meant to make available to a party wishing to engage in potentially infringing conduct, Congress did not mean to make avail-

able to parties who had purchased immunity from infringement actions.[3]

GPhA asserts that 2003 amendments to the Hatch-Waxman Act "confirmed" the Declaratory Judgment Act's policy in favor of allowing a party wishing to engage in potentially infringing activity to seek a prospective declaration of non-infringement or invalidity. GPhA Br. 7-9. In fact, notwithstanding GPhA's incantation of Congress' desire to foster "patent certainty," *id.* at 8, Congress affirmed its intent to preserve the "reasonable apprehension" test as developed by the courts, and to preclude Declaratory Judgment Actions by potential infringers based on the simple fact that the patentee had not sued.

In the 2003 amendments, Congress provided that when an ANDA includes a paragraph IV certification, and neither the NDA holder nor the patent owner has brought an action for infringement of the patent before the expiration of 45 days after notice of the paragraph IV certification was received, the federal courts have subject matter jurisdiction in a suit brought under the Declaratory Judg-

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[3] "Congress is understood to legislate against a background of common-law . . . principles." *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991). When Congress enacted the Declaratory Judgment Act in 1934, the common-law principle of licensee estoppel barred a nonbreaching licensee from challenging the patent. To have authorized a suit such as this would have meant abrogating that principle. *See* ABA Br. 6-10. But "[i]n order to abrogate a common-law principle, [a] statute must 'speak directly' to the question addressed by the common law." *United States* v. *Texas*, 507 U.S. 529, 534 (1993) (citation omitted). In enacting the Declaratory Judgment Act, Congress did not "speak directly" to that issue.

ment Act to the extent consistent with the Constitution.[4] The Conference Report sets out Congress's intent with respect to "reasonable apprehension":

> DECLARATORY JUDGMENTS
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> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to 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.
>
> Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. *See, e.g.*, *Fina Oil & Chem. Co.* v. *Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.
>
> In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45

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[4] Pub. L. No. 108-173, Tit. IX, § 1101(a)(2)(C), 117 Stat. 2450 (2003) (codified at 21 U.S.C. § 355(j)(5)(C)(i)); § 1102(b)(2)(D), 117 Stat. 2454 (2003) (codified at 21 U.S.C. § 355(c)(3)(C)); § 1101(d), 117 Stat. 2457 (2003) (codified at 35 U.S.C. § 271(e)(5)).

> days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. *See, e.g.*, *Vanguard Research, Inc.* v. *Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002). 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.

Conference Report, H.R. Rep. No. 108-391, at 836 (2003) (emphasis added). *See Apotex, Inc.* v. *Pfizer Inc.*, 385 F. Supp. 2d 187, 193 (S.D.N.Y. 2005) (discussing legislative history of 2003 amendment), *aff'd*, *Apotex, Inc.* v. *Pfizer, Inc.*, 199 Fed. Appx. 1013 (Fed. Cir. 2005) (per curiam), *petition for cert. pending*, No. 05-1006.[5]

Of course, the policy reflected in these amendments – to allow an ANDA applicant to pursue a declaratory judgment action where it has a "reasonable apprehension" of suit – resonates in this case. The mere fact that an infringer faces potentially significant liability by virtue of the patentee's ability to enforce its patent does not give rise to a case or controversy. Taking into account the totality of the circumstances, there must be conduct that gives rise to a "reasonable apprehension" suit, and that is absent where, as here, the party seeking declaratory relief has purchased immunity from an infringement action. Such a party is legally entitled to practice the patented invention under the license agreement and therefore has no need of declaratory relief.

## CONCLUSION

For the foregoing reasons, the judgment should be affirmed.

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[5] On May 15, 2006, the Court invited the Solicitor General to file a brief in this case expressing the views of the United States.

Respectfully submitted,

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