No. 05-608

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

GENENTECH, INC., *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF *AMICUS CURIAE* OF THE GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Generic Pharmaceutical Association ("GPhA") represents over 120 companies that manufacture more than ninety percent of all affordable prescriptions dispensed in the United States each year, accounting for more than one billion prescriptions annually.

[1] Letters evidencing the parties' consent to the submission of this brief have been lodged with the Clerk. Pursuant to this Court's Rule 37.6, *amicus* states that no counsel to a party authored this brief in whole or in part and no person other than *amicus* and its members made a financial contribution towards the preparation and submission of the brief.

Generic drug companies have a vital interest in this case because the ability of generic drug companies to bring declaratory judgment actions against holders of pharmaceutical patents is critical to their ability to bring less expensive generic pharmaceuticals to market quickly. Congress explicitly authorized such declaratory judgment actions when it amended the Hatch-Waxman Act in 2003 to permit generic companies to bring a civil action "to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C).

The reasoning applied by the Federal Circuit in this and other cases has effectively prevented generic drug companies from pursuing declaratory judgment actions even in situations in which Congress has expressly authorized them. In *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333, *reh'g en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) ("*Teva v. Pfizer*"), the Federal Circuit upheld the dismissal of a declaratory judgment action brought by a generic drug company, ruling that Article III precluded subject matter jurisdiction unless the plaintiff demonstrates that it faces a "reasonable apprehension of imminent suit" by the patentee. In this case, the Federal Circuit applied the same "reasonable apprehension" test to preclude petitioner's declaratory judgment action. In both cases, and in many other patent declaratory judgment actions, a justiciable controversy was unquestionably presented under this Court's Article III jurisprudence.

GPhA has been permitted to submit *amicus* briefs in both the Federal Circuit and in this Court to urge the recognition that declaratory judgment actions by generic companies are essential components of the country's efforts to moderate the ever-increasing costs of prescription drugs and fall comfortably within this Court's standards of justiciability under

Article III.[2] GPhA submits this brief to stress the untoward impact that the "reasonable apprehension" requirement has on a wide range of cases that do not involve the licensing of patents and its inconsistency with Article III, the Declaratory Judgment Act, and the patent laws.

SUMMARY OF ARGUMENT

The Federal Circuit erred in ruling that MedImmune had failed to demonstrate the existence of a justiciable "actual controversy," as required by Article III and the Declaratory Judgment Act, because MedImmune faced no "reasonable apprehension" of a patent infringement suit by Genentech. *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964-65 (Fed. Cir. 2005), *cert. granted*, 126 S. Ct. 1329 (2006). The court of appeals erred because its "reasonable apprehension of suit" requirement undermines one of the principal purposes of the Declaratory Judgment Act and finds no support in this Court's Article III jurisprudence.

The Declaratory Judgment Act was enacted to provide a mechanism for a party to obtain definitive judicial resolution of legal claims where claimants *refuse* to bring suit. Congress sought to relieve a prospective defendant of the Hobson's Choice between incurring mounting potential liability and foregoing legitimate business or other opportunities. The Federal Circuit's insistence that the declaratory judgment plaintiff reasonably apprehend the imminent commencement of litigation before seeking relief from such a dilemma effectively eliminates the possibility of relief in the situations in which Congress intended such relief to be available.

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[2] GPhA submitted *amicus* briefs in this Court in support of the certiorari petitions in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, No. 05-48 (*cert. denied* on Oct. 11, 2005) and *Apotex, Inc. v. Pfizer, Inc.*, No. 05-1006 (*petition for certiorari filed* Feb. 9, 2006). It submitted *amicus* briefs in the Federal Circuit in *Teva v. Pfizer*.

The reasonable apprehension of suit requirement is inconsistent with this Court's Article III decisions. The only Article III requirement for declaratory judgment actions is that the dispute sought to be resolved be "definite and concrete, touching the legal relations of parties having adverse legal interests," "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." *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 241 (1937).

The Article III requirements are met in this case. The constitutional standard is also met in declaratory judgment actions brought by generic drug companies pursuant to the 2003 amendments to the Hatch-Waxman Act that authorized generic companies to bring a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C)(i)(II), and directed district courts to exercise subject matter jurisdiction over such claims "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). However, the Federal Circuit's application of the "reasonable apprehension" test has effectively reduced these amendments to a dead letter by precluding any successful prosecution of such actions.

The Federal Circuit's application of the "reasonable apprehension" test in this case is not saved because the patent licensor is unable to bring suit against the licensee until the licensee breaches the license. This Court has permitted declaratory judgment actions to proceed even where the underlying claim of the declaratory judgment defendant against the declaratory judgment plaintiff has not accrued. The Federal Circuit's reliance on what it referred to as "equalizing principles" is therefore misplaced.

Because MedImmune asserted an "actual controversy," the Federal Circuit's decision should be reversed.

ARGUMENT

I. CONGRESS INTENDED TO PERMIT PARTIES TO SEEK RESOLUTION OF PATENT DISPUTES WHERE PATENTEES DECLINE TO BRING INFRINGEMENT ACTIONS.

A. The Declaratory Judgment Act.

The Declaratory Judgment Act was enacted in 1934 in large part to permit parties to obtain definitive judicial determinations of non-infringement and invalidity in patent disputes in which the patentee chooses *not* to initiate patent infringement litigation. As Congress recognized, before the Declaratory Judgment Act such parties faced a Hobson's Choice between commencing (or continuing) potentially infringing conduct (and thereby risking often ruinous liability) or foregoing legitimate business opportunities (if the parties or their customers found the risks of liability unacceptably high).[3] The Declaratory Judgment Act was intended to provide a mechanism for parties to avoid that dilemma by obtaining a definitive judicial resolution *before* commencing or continuing potentially infringing conduct.

In *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 95-96 (1993), this Court underscored the importance of declaratory judgment actions in resolving

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[3] *See* S. Rep. No. 73-1005, at 2 (1934) (citing declaratory judgment action's utility in "avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages"); Hearings Before a Subcomm. of the S. Comm. on the Judiciary on H.R. 5623, 70th Cong. 35 (1928) (statement of E.R. Sunderland) (citing Hobson's Choice faced by manufacturers of potentially patented devices); Hearing Before the H. Comm. on the Judiciary on H.R. 5030, H.R. 10141, H.R. 10142, and H.R. 10143, 67th Cong. 10 (1922) (statement of Henry W. Taft, American Bar Association) (noting utility of declaratory judgment actions in patent disputes).

patent disputes in which the patentee is *not* about to bring suit. This Court referred to

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act (Act), 28 U.S.C. § 2201. In the patent version of that scenario, a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword . . . . Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the patent owner refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests. The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.

Id. at 95-96 (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988)). This Court went on to note that the desire of a company to "avoid the threat of a 'scarecrow' patent . . . may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Id.* at 96.

The phrase "scarecrow patent" derives from Judge Learned Hand's opinion in *Bresnick v. United States Vitamin Corp.*, 139 F.2d 239 (2d Cir. 1943). In that case, although the patentee sued the defendant only on one claim of its patent, the court ruled that the patent in its entirety was invalid. Judge Hand observed, "[w]e have disposed of the patent as a whole because it has seemed to us proper that it should not remain in the art as a scarecrow." *Id.* at 242. A scarecrow patent is one that is *not* asserted by the patentee in an infringement action, but nevertheless serves to "scare off" potential customers of the patentee's competitors. The point of this Court's reference to "scarecrow patents" in *Cardinal*

Chemical was that the Declaratory Judgment Act was meant to provide a means to eliminate the competitive barriers caused by such patents by allowing potential infringers to obtain "patent certainty" even where there is no infringement claim asserted.[4]

B. The Hatch-Waxman Act And Its 2003 Amendments.

Congress confirmed the important role of declaratory judgment actions in offering "patent certainty" to parties faced with the "*in terrorem* choice" to which this Court referred in *Cardinal Chemical* when it amended the Hatch-Waxman Act in 2003 to create a "civil action to obtain patent certainty" for a generic drug company that files an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(5)(C).

As enacted in 1984, the Hatch-Waxman Act gave the holder of a pharmaceutical patent the right to sue an ANDA applicant immediately for patent infringement if the ANDA applicant sought FDA approval to launch a generic formulation of the pioneer drug before the expiration of the patent. 35 U.S.C. § 271(e)(2)-(4); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675-78 (1990). Congress created this statutory act of infringement to permit the resolution of patent disputes before the expiration of potentially blocking patents and thereby to accelerate the introduction of less expensive generic drugs. *Eli Lilly*, 496 U.S. at 676-78.

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[4] *Accord Clair v. Kastar, Inc.*, 148 F.2d 644, 646 (2d Cir. 1945) (L. Hand, J.). In *Clair*, the court stressed that the Declaratory Judgment Act provides a remedy to potential infringers that believe themselves to be harmed by a patentee's delay in asserting an infringement claim:

> [I]f 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.*

Id. (emphasis added).

By 2003, however, Congress recognized that some drug companies had sought to "delay infringement litigation between generic drug manufacturers and pioneer drug companies," H.R. Conf. Rep. No. 108-391, at 836 (2003), and thereby deny the public the benefit of less costly generic drugs, *see Eli Lilly*, 496 U.S. at 676. In response, Congress expressly extended to ANDA applicants the same opportunity to initiate early judicial resolution of patent disputes that the original Hatch-Waxman Act gave to patentees. The 2003 legislation authorized ANDA applicants to bring a "civil action to obtain patent certainty" for a declaration of patent invalidity or non-infringement, if the patentee had not commenced an infringement action within 45 days of the infringing ANDA filing. 21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5).

This statutory leveling of the playing field never had a chance to work. In *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333, *reh'g en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) ("*Teva v. Pfizer*"), the first case to reach the Federal Circuit under the new law, the court of appeals ruled that Article III itself requires that an ANDA applicant suing to obtain patent certainty prove that it faces a "reasonable apprehension of imminent suit" by the patentee, a situation that will almost never exist when there has been no action commenced within 45 days of the ANDA filing. The Federal Circuit thus precluded "civil action[s] to obtain patent certainty" in the only situations in which they were intended to be available. In effect, the court of appeals ruled that the Constitution precluded Congress from leveling the playing field.[5]

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[5] The *Teva v. Pfizer* majority expressed the view that its holding was consistent with Congress' intent, 395 F.3d at 1336, but this view makes no sense. Initially, it was pure dictum because if, as the court held, Article III requires a "reasonable apprehension of imminent suit," then it obviously does not matter what Congress intended to do. Beyond that, the upshot of

This effective nullification of the statutory "civil action to obtain patent certainty" will result in delays in introducing many generic drugs, delays that will have a significant, negative impact on the nation's health care system. Data published by the federal Centers for Medicare & Medicaid Services indicate that national expenditures for prescription drugs have risen from $12 billion in 1980 to $188.5 billion in 2004.[6] Generic drugs play a critical role in moderating this explosive growth in the cost of prescription drugs. A study published by the Federal Trade Commission in 2002 reported that average drug prices declined 20 percent within two years of generic drug entry into the market and that the savings increase with the number of generic competitors.[7]

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the *Teva v. Pfizer* court's reasoning was that, by creating a new "civil action to obtain patent certainty," Congress intended to permit declaratory judgment actions in precisely the same circumstances in which they were permitted under Federal Circuit precedent before the legislation was passed. Congress does not usually enact legislation in order to preserve the legal status quo.

The conference committee report cited by the court of appeals, *id.* at 1336-37, shows that the conferees expected the courts to apply the reasonable apprehension test if, but only if, the Constitution required it, but expressed no views on whether the constitution required it, a decision reserved for the judicial branch. Such an expectation reflected the command set forth in the legislation that district courts exercise jurisdiction over declaratory judgment actions brought by ANDA applicants "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

[6] These data can be found at http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf.

[7] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 9 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

II. THE FEDERAL CIRCUIT'S "REASONABLE APPREHENSION OF SUIT" REQUIREMENT IS INCONSISTENT WITH THE COURT'S ARTICLE III JURISPRUDENCE.

A. The Constitution And The Declaratory Judgment Act Require An "Actual Controversy".

The "actual controversy" requirement in the Declaratory Judgment Act "manifestly has regard to [Article III] and is operative only in respect to controversies which are such in the constitutional sense." *Aetna*, 300 U.S. at 239-40. As this Court stated in *Aetna*, a claim for declaratory relief is justiciable if it is "definite and concrete, touching the legal relations of parties having adverse legal interests," "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." *Id.* at 240-41.

This Court later crystallized this "irreducible constitutional minimum" in terms of the now familiar requirements of injury in fact, traceable to the conduct of the defendant and redressable by the requested relief. *Bennett v. Spear*, 520 U.S. 154, 162 (1997). *Accord Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998). *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 79 (1978) ("We ... cannot accept the contention that ... a litigant must demonstrate something more than injury in fact and a substantial likelihood that the judicial relief requested will prevent or redress the claimed injury to satisfy the 'case or controversy' requirement of Article III."). Although the Court in *Bennett* and *Steel Co.* articulated this standard as a "standing" requirement, it serves as the irreducible minimum requirement of Article III for related justiciability doctrines such as ripeness. *See Duke Power*, 438 U.S. at 81.

B. The Federal Circuit's Two-Part Test For Jurisdiction In Declaratory Judgment Actions Requires More Than An "Actual Controversy".

In cases in which a declaratory judgment plaintiff seeks a declaration that a patent is invalid or not infringed by the product that the plaintiff proposes to sell, the Federal Circuit has formulated its own two-part test ostensibly to implement the requirements of Article III.

1. *This case presents no issue concerning the first element of the Federal Circuit's jurisdictional test.*

The first element of the Federal Circuit's test is that the declaratory judgment plaintiff have engaged in "activity . . . which could constitute infringement, or concrete steps taken with the intent to conduct such activity." *Teva v. Pfizer*, 395 F.3d at 1332 (citing *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir.), *cert. dismissed*, 543 U.S. 941 (2004)).

Although in this case the Federal Circuit did not discuss this first part of its test for an "actual controversy," MedImmune plainly satisfied it. It was marketing a specific drug, Synagis®, that Genentech claimed was within the scope of its patents. Moreover, whether Synagis® does in fact infringe those patents (or would infringe absent a license) and whether Genentech's patents are valid are "definite and concrete" questions that "touch[] the legal relations of parties having adverse legal interests," and "admit[] of specific relief through a decree of a conclusive character," *i.e.*, a declaration that specific patents are or are not valid and that a specific product (Synagis®) does or does not infringe them. MedImmune is clearly eager to sell its product immediately without paying royalties. Genentech is just as clearly unwilling to permit it to do so. MedImmune is paying royalties "under protest," and its declaratory judgment action seeks to "lift the

heavy hand of that tribute." *Altvater v. Freeman*, 319 U.S. 359, 365 (1943).

2. *The second element of the Federal Circuit's jurisdictional test is required neither by Article III nor by the Declaratory Judgment Act.*

The second requirement of the Federal Circuit's test for an actual controversy is "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," *Teva v. Pfizer*, 395 F.3d at 1332. The Federal Circuit requires that the infringement suit be "imminent." *Id.* at 1333. The Federal Circuit found MedImmune unable to satisfy this requirement because it remained in compliance with its license from Genentech, albeit under protest, and therefore faced no apprehension of suit. *MedImmune*, 427 F.3d at 964-65.

MedImmune argues to this Court that, whatever the merits of requiring a reasonable apprehension of imminent litigation in general, it should not bar a declaratory judgment action brought by a licensee simply because the licensee remains in compliance with the terms of the license. According to MedImmune, the Federal Circuit's categorical requirement that a licensee stop paying royalties before seeking a declaration of invalidity or non-infringement goes too far where, as here, the Article III requirements of an actual controversy genuinely admitting of specific relief by a decree of a conclusive character were satisfied.

MedImmune's arguments are correct as far as they go, but they do not go far enough. The "reasonable apprehension of imminent suit" requirement *itself* constitutes an unwarranted limitation on the jurisdiction of every district court in the United States in patent cases. It prevents the resolution of disputes that satisfy the requirements of Article III and

thwarts the purposes of both the Declaratory Judgment Act itself and the recent Hatch-Waxman Act amendments.

C. Article III Controversies Often Arise Even When The Patentee Is Not About To Commence An Infringement Action.

There are many circumstances in which a patentee will not be on the verge of commencing patent infringement litigation despite the occurrence of arguably infringing conduct or the existence of other facts that create a justiciable Article III controversy. A principal purpose of the Declaratory Judgment Act is to provide a procedural mechanism for the declaratory judgment plaintiff to obtain a binding judicial resolution of a dispute in precisely those circumstances. This Court recognized this in *Cardinal Chemical*, 508 U.S. at 95-96.

For example, courts have recognized that patentees who face numerous infringers may sue sequentially rather than undertake multiple infringement actions simultaneously. The legitimacy of a patentee's pursuing its infringement claims seriatim has served to defeat the defense of laches to a delayed infringement claim. *See, e.g., Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1293 (Fed. Cir. 1992); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 876-77 (Fed. Cir. 1991); *Clair v. Kastar, Inc.*, 148 F.2d 644, 646 (2d Cir. 1945). Significantly, many of these cases have noted that an alleged infringer can avoid any prejudice from such delay by bringing a declaratory judgment action, which is assumed to be available even though the alleged infringer cannot reasonably apprehend imminent infringement litigation. 6 CHISUM ON PATENTS §19.05[2][d], at 19-641 & n.204 (2006) (citing cases).

A further example of particular concern to *amicus curiae* arises in the generic drug approval process set forth in the Hatch-Waxman Act. Developers of new drugs must list in an

FDA publication (commonly referred to as the "Orange Book") all patents that could "reasonably" be asserted against generic formulations of the drugs. 21 U.S.C. § 355(b)(1)(G), (c)(2). *See Teva v. Pfizer*, 395 F.3d at 1328. If a generic drug company files an ANDA with respect to such a drug, it must certify as to every Orange Book patent for that drug whether the generic company seeks to launch before the expiration of such patent on the ground that the patent is invalid or would not be infringed by its generic formulation. As noted above, that certification constitutes an "act of infringement" sufficient to trigger jurisdiction over a patent infringement suit by the patentee. 35 U.S.C. § 271(e); *Eli Lilly*, 496 U.S. at 678. If the patentee commences litigation within 45 days of the ANDA applicant's certification, then FDA approval of the ANDA is automatically stayed for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

While the prospect of a 30-month stay of FDA approval is often sufficient incentive to the patentee to bring suit, there are many circumstances in which it is in the interests of the patentee to lie low. *Teva v. Pfizer* is illustrative. The generic drug company, Teva, filed an ANDA with respect to Pfizer's blockbuster anti-depressant, Zoloft®, in 2002. Pfizer listed two patents for Zoloft® in the Orange Book. One expired in 2006 and the other in 2010. Teva challenged only the second. That constituted an act of infringing the second patent sufficient to support an immediate infringement action by Pfizer against Teva under 35 U.S.C. § 271(e).

But Pfizer had no incentive to sue. Although Pfizer would likely do whatever it could to maintain its multi-billion dollar Zoloft® monopoly as long as possible, the 30-month stay of FDA approval was itself worth nothing to Pfizer because Teva had not challenged the patent that would expire four years later in 2006 and the FDA would not approve Teva's ANDA before that expiration, more than 30 months after Teva filed its ANDA. Moreover, by suing Teva, Pfizer

would create a risk that Teva would prevail and thereby eliminate any risk created by the patent for other generic companies. *See Teva v. Pfizer*, 395 F.3d at 1330.

When Pfizer failed to sue within 45 days of its ANDA, Teva brought an action for a declaration of invalidity and/or non-infringement of the later expiring patent. The case was justiciable under this Court's Article III jurisprudence.

Initially, if Pfizer had sued Teva under 35 U.S.C. § 271(e), the case plainly would have been a justiciable patent infringement action. Yet as this Court has ruled, "[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 Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (emphasis added). *See also Aetna*, 300 U.S. at 244 ("[T]he character of the controversy ... is essentially the same whether it is presented by the insured or by the insurer.... It is the nature of the controversy, not ... the particular party who presents it, that is determinative."). *See* 10B Charles A. Wright *et al.*, FEDERAL PRACTICE AND PROCEDURE § 2757, at 475 (1998) ("There is little difficulty in finding an actual controversy if all of the acts that are alleged to create liability already have occurred.").

Moreover, application of the principles set forth in *Aetna* confirmed that the controversy raised by Teva was justiciable. Teva had filed its ANDA announcing its intent to launch on the expiration of Pfizer's first Zoloft® patent. Teva's certification had statutorily infringed Pfizer's second Zoloft® patent. Its suit presented a "case admitting of an immediate and definitive determination of the legal rights of the parties." *Aetna*, 300 U.S. at 241. The controversy was "definite and concrete, touching the legal relations of parties having adverse legal interests." *Id.* at 240-41. The district court would have faced "no difficulty ... in passing a conclusive decree applicable to the facts found and to the obligations of the

parties corresponding to those facts." *Id.* at 243. The suit called, "not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242.

Despite the ready fit of Teva's suit under this Court's articulated criteria for Article III justiciability, and notwithstanding that this Court has "emphasized the importance to the public at large of resolving questions of patent validity,"[8] the Federal Circuit applied its "reasonable apprehension" requirement and threw out Teva's suit.

As a result of this ruling, complaints seeking to assert the "civil action to obtain patent certainty" that Congress created in 2003 are now routinely dismissed for want of subject matter jurisdiction.[9]

The Federal Circuit's decisions do not ground the "reasonable apprehension" requirement in the Article III jurisprudence of this Court. The stated rationale for the "reasonable apprehension" requirement turns, at least in substantial part, on the Federal Circuit's concern for protecting "quiescent" patentees.[10] In *Hunter Douglas, Inc. v. Harmonic*

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[8] *Cardinal Chem.*, 508 U.S. at 100.

[9] *E.g.*, *Apotex, Inc. v. Pfizer, Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y.), *aff'd*, 159 Fed. Appx. 1013 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3476 (U.S. Feb. 6, 2006) (No. 05-1006); *Mylan Pharm. Inc. v. Merck & Co.*, No. 05-1416, 2005 WL 2850137 (M.D. Pa. Oct. 28, 2005); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. 05-2881, 2005 WL 3619389 (D.N.J. Dec. 12, 2005), *appeal docketed*, No. 06-1181 (Fed. Cir. Jan. 18, 2006); *Eon Labs, Inc. v. Pfizer, Inc.*, No. 05-0002, 2005 WL 1705295 (S.D.N.Y. July 19, 2005). A petition seeking review of a Federal Circuit decision affirming such a dismissal is presently pending before this Court. *Apotex, Inc. v. Pfizer, Inc.*, No. 05-1006. *Amicus* GPhA has filed in support of grant of the petition in that case.

[10] Another "part" is the Federal Circuit's asserted preference for not permitting declaratory judgments to be brought where the declaratory

Design, Inc., 153 F.3d 1318, 1326 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999), the Federal Circuit noted that it applied the reasonable apprehension requirement *because* that rule "protects quiescent patent owners against unwarranted litigation" under the patent laws. *Id.* (quoting *Arrowhead,* 846 F.2d at 736).

The desire to spare "quiescent" patentees the bother of defending declaratory judgment actions brought by parties who have made a substantial investment in potentially infringing technology may or may not be well-founded as a matter of policy,[11] but it has nothing to do with the justiciability of the controversy itself. Justiciability is a function of the underlying legal claim, regardless of which party initiates its judicial resolution. The justiciability of a claim is unaffected by the claimant's enthusiasm for asserting it, especially where the claimant insists on reserving its rights and leaving the other side up in the air.

Indeed, where the patentee has concluded that the costs of *prosecuting* patent litigation exceed the benefits of litigation, but the benefits of leaving competitors and customers uncertain as to their rights are nonetheless worth retaining, the patent has become a "scarecrow." As noted above, this Court has pointed to the "scarecrow" patent situation as a

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judgment defendant is not equally able to initiate a suit to resolve the dispute with the plaintiff. *See infra* pp. 18-20.

[11] These burdens are modest. A patentee who concludes that the declaratory judgment plaintiff's product does not infringe can easily avoid the litigation by the expedient of formally acknowledging that conclusion. Such an acknowledgment or a formal covenant not to sue the declaratory judgment plaintiff for infringement will estop the patentee from ever bringing an infringement action against the plaintiff with respect to that product and will result in the divestiture of subject matter jurisdiction. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995).

paradigmatic occasion for applying the Declaratory Judgment Act. *Cardinal Chem.*, 508 U.S. at 96. Accordingly, the Federal Circuit's "reasonable apprehension of imminent suit" requirement arises out of a policy at odds with the fundamental principles of Article III as well as the legislative policy of the Declaratory Judgment Act itself.

D. The Inability Of Genentech To Bring An Infringement Action Is No Reason To Deny MedImmune The Right To Bring A Declaratory Judgment Action.

The court of appeals declined to follow the principles of *Cardinal Chemical* in this case because Genentech, unlike the owner of a "scarecrow" patent, could not bring an infringement action because of its license to MedImmune. The court adverted to "the equalizing principles that underlie the Declaratory Judgment Act," *MedImmune*, 427 F.3d at 964, principles that the court had earlier elaborated in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1382 (Fed. Cir. 2004). In *Gen-Probe,* the Federal Circuit found it "undesirable" to permit a licensee in good standing to bring a declaratory judgment action because it would shift "all the risk" to the patentee/licensor "while the licensee would benefit from the license's effective cap on damages or royalties in the event its challenge to the patent's scope of validity fails." *Id.*

The Federal Circuit's insistence that a declaratory judgment action will lie only when the underlying infringement claim has accrued is not grounded in the Article III jurisprudence of this Court, and the Federal Circuit made no pretense to the contrary. This Court has not applied these "equalizing principles." For example, in *Maryland Casualty,* this Court permitted a liability insurance company to bring a declaratory judgment action against the plaintiff in a tort suit against the company's insured before there had been a resolution of the tort suit. The Court noted that the tort plaintiff did not have a direct action against the insurer

because the underlying tort suit had not been resolved. *Maryland Casualty*, 312 U.S. at 273. Nevertheless, despite the asymmetry of allowing the insurer to sue the tort plaintiff for a declaratory judgment when the tort plaintiff could not sue the insurer and might never be able to sue the insurer, this Court permitted the declaratory judgment action to proceed.

Moreover, this Court has frequently allowed plaintiffs to challenge the constitutionality of statutes as an alternative to violating them and raising their invalidity as a defense to an enforcement action. *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979); *Times Film Corp. v. Chicago*, 365 U.S. 43, 45-46 (1961). Here, too, there is no application (or even consideration) of the Federal Circuit's "equalizing principles." On the contrary, the Court has recognized the advantage of applying the Declaratory Judgment Act precisely to spare plaintiffs the need to expose themselves to an enforcement action. *See Steffel v. Thompson*, 415 U.S. 452, 459 (1974). Application of the Federal Circuit's "equalizing principles" would require the dismissal of these declaratory judgment actions because the government had no corresponding ability to enforce its laws before the declaratory judgment plaintiff violated them.

The Federal Circuit itself applies these "equalizing principles" in a highly selective manner, as its treatment of declaratory judgment actions in the ANDA setting demonstrates. Congress created the "civil action to obtain patent certainty" specifically to equalize the opportunity of innovator and generic drug companies to obtain "patent certainty" before patent expiration and generic launch. District courts have routinely entertained, and the Federal Circuit has routinely reviewed, cases brought by patentees predicated upon the "technical act of infringement" of submitting an ANDA that challenges the innovator's patent. Yet the Federal Circuit ruled in *Teva v. Pfizer* that Article III precludes

the resolution of the identical controversies at the behest of generic drug companies if the patentee has not overtly threatened an infringement action.

The Federal Circuit's reliance on "equalizing principles," like its insistence on proof of a "reasonable apprehension of imminent suit," is nothing more than an attempt to engraft policy limitations, alien to this Court's jurisdiction cases, onto Article III. The Federal Circuit is wrong as a matter of constitutional law.

CONCLUSION

The Federal Circuit's decisions in this case and other declaratory judgment actions are inconsistent with the Article III decisions of this Court, the purposes of the Declaratory Judgment Act, and the 2003 amendments to the Hatch-Waxman Act. The "reasonable apprehension" rule prevents the resolution of justiciable controversies not only in cases involving licensees but in many other patent disputes, including cases seeking to accelerate the launch of generic drugs. This Court should reverse the decision of the Federal Circuit in this case and make it clear that the "reasonable apprehension" test is not constitutionally required and may not be applied to prevent the resolution of declaratory judgment actions seeking declarations of patent invalidity or non-infringement.

Respectfully submitted,

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