No.

In the Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This is one of many suits brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer.

The Question Presented is whether such a suit states a justiciable controversy when, as in this case, the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.

LIST OF PARTIES

All parties in the proceedings below are listed in the caption to this Petition.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parent company of Apotex Inc. is Apotex Pharmaceutical Holdings, Inc. The parent company of Apotex Corp. is Apotex Holdings, Inc. There is no publicly-held corporation that owns 10% or more of either Apotex Inc. or Apotex Corp.

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The decision of the United States Court of Appeals for the Federal Circuit (App. 1a)[1] for which review by this Court is sought is available at No. 05-1199, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005). The decision of the United States District Court for the Southern District of New York that was reviewed by the Federal Circuit (App. 2a-15a) is reported at 385 F. Supp. 2d 187 (S.D.N.Y. 2005).

JURISDICTION

The judgment of the Federal Circuit for which review by this Court is sought was entered on December 12, 2005. This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, art. III, § 2, cl. 1 provides in pertinent part:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; . . . .

(App. 69a.)

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[1] References to "App. ___" are to the Appendix attached hereto, as required under Supreme Court Rule 14.1(i).

21 U.S.C.A. § 355(j)(5)(C)(i)(II) (West Supp. 2005) provides:

> **(C) Civil action to obtain patent certainty-**
>
> **(i) Declaratory judgment absent infringement action-**
>
> * * *
>
> **(II) Filing of civil action-** If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . .

(App. 70a-71a.)

35 U.S.C.A. § 271(e)(5) (West Supp. 2005) provides:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of

> which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(App. 74a.)

STATEMENT OF THE CASE

1. This petition arises from a patent dispute between respondent Pfizer and petitioner Apotex. Pfizer has patents relating to sertraline hydrochloride, which it sells as an anti-depressant under the brand-name Zoloft®, and which generates more than $3 billion in annual sales. Apotex has developed a generic version of Zoloft® that it seeks to market.

Relevant here, Pfizer has listed with the FDA two patents in connection with Zoloft®: one expires in 2006 ("the '518 patent")[2]; the other ("the '699 patent"), which Pfizer has said expires in 2010. Apotex followed the statutory procedure for launching its generic equivalent to Zoloft®. It submitted to the FDA an Abbreviated New Drug Application (ANDA). Apotex represented that it would begin selling its drug after the '518 patent expired in 2006.

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[2] The '518 patent actually expired on December 30, 2005, but Pfizer obtained a 6-month regulatory exclusivity period attaching to that patent. *See* 21 U.S.C. § 355a. That period ends on June 30, 2006.

Apotex further represented that the later-expiring '699 patent would not be infringed or was invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "Paragraph IV certification").

Pfizer previously has been quite aggressive in defending its intellectual property. It did not, however, sue Apotex precisely in order to prevent the marketing of a generic equivalent to Zoloft®. *See* 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271(e)(2)(A) (making the submission of a Paragraph IV certification a statutory act of patent infringement). The failure to resolve the patent controversy specifically created a substantial cloud of uncertainty over Apotex's ability to enter the marketplace because Apotex faced potentially crippling patent liability. In addition, the failure to secure a court judgment of non-infringement or invalidity precluded Apotex as a matter of law from selling its drug until *at least* 180 days after the expiration of the '518 patent.[3]

Congress has enacted a statutory scheme specifically designed to prevent brand-name manufacturers from delaying generic market entry with such tactics. Federal law

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[3] Apotex will be delayed at least 180 days after expiration of the '518 patent. Federal law grants the first generic manufacturer to file an ANDA containing a Paragraph IV certification (in this case, Ivax Pharmaceuticals) the right to sell its products as the only generic competitor for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). If Apotex secured a judgment that the '699 patent was invalid or not infringed, the expiration of the 180-day period for that patent would begin to run immediately, rather than upon Ivax's first commercial marketing. *Id.* But because, absent a court decision on the '699 patent, Ivax's exclusivity will not begin to run until it begins marketing its product, Apotex could be precluded from marketing far longer than 180 days after the '518 patent expires. This would happen if Ivax, for any reason, decided not to immediately begin marketing its product on June 30, 2006.

provides that Pfizer's submission of the '699 patent to the FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" based on this patent against a generic competitor. 21 U.S.C. § 355(b)(1). Further, Apotex's filing of its Paragraph IV ANDA constituted a statutory act of patent infringement of the '699 patent. 35 U.S.C. § 271(e)(2)(A). In such circumstances, Congress specifically conferred on the federal courts jurisdiction over a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II)) and directed that such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).

2. Apotex accordingly brought this declaratory judgment suit against Pfizer in the Southern District of New York alleging that its generic equivalent would not infringe the '699 patent or that the '699 patent was invalid. The district court acknowledged that Pfizer had represented that the '699 patent was enforceable against generic equivalents of Zoloft®, whereas Apotex took the opposite position and submitted an ANDA that constituted a statutory act of patent infringement. (App. 6a-7a.) And the district court did not doubt that Apotex's inability to enter the marketplace based upon a failure to resolve the patent controversy injured Apotex. Indeed, the district court recognized this "gaming of the system" by brand-name manufacturers. (App. 4a.) The practice of companies such as Pfizer of "'parking' the 180-day marketing exclusivity period" has the effect of "indefinitely delaying" generic competition. (App. 5a.) Congress had specifically conferred on generic manufacturers the right to sue, and the obligation of the federal courts to resolve those actions, "[t]o curb these abuses." (*Id.*)

The district court nonetheless held that it was required by Federal Circuit precedent to dismiss the suit for lack of a justiciable case or controversy because Apotex did

not have a "reasonable apprehension" that it would be sued by Pfizer. (App. 12a-15a.)

3. The Federal Circuit had exclusive jurisdiction over Apotex's appeal. 28 U.S.C. § 1295(a)(1). While the appeal was pending, that court decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (App. 16a-49a), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005) (App. 50a-68a), *and cert. denied*, 126 S. Ct. 473 (2005). *Teva* concerned the justiciability of another manufacturer's declaratory judgment action against Pfizer regarding this same drug product – a generic competitor to Zoloft®. Teva, joined by AARP and the Federal Trade Commission as *amicus curiae* (*see* http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf), argued that a justiciable case or controversy existed on these recurring facts.

A divided panel of the Federal Circuit, tightening its already rigorous requirement for finding a justiciable case or controversy, held that a court may adjudicate a declaratory judgment action only if the generic competitor faces an "*imminent*" suit by a brand-name manufacturer. *Teva*, 395 F.3d at 1333 (App. 30a). Like the district court in this case, the Federal Circuit in *Teva* did not doubt that a generic manufacturer is directly and immediately injured by this state of affairs. Rather it was dispositive that "Teva virtually concedes that Pfizer will not bring immediate suit" because it "does not wish to expose the patent to the possibility of a noninfringement or invalidity determination." *Id.* at 1333-34 (App. 31a).

The Court simply deemed irrelevant as a matter of law the clear and actual controversy between the parties and the concrete injury suffered by Teva:

> The fact that Teva is disadvantaged from a business standpoint . . . and the fact that Pfizer's decision not to sue Teva creates an

> impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

395 F.3d at 1338 (App. 40a) (emphasis added). It continued:

> [I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage . . . . Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

Id.

Teva, again joined by the FTC as *amicus curiae* (*see* http://www.ftc.gov/ogc/briefs/050208teva.pdf), sought rehearing en banc. The court of appeals denied rehearing by a divided vote and over vigorous dissenting opinions. *Teva*, 405 F.3d at 991-96 (App. 52a-61a) (Gajarsa, J., dissenting); *id.* at 996-99 (App. 61a-68a) (Dyk, J., dissenting).[4]

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[4] In response to Teva's petition for certiorari, Pfizer argued that no controversy existed on the facts of that particular case for a unique

4. Pfizer argued that this appeal was controlled by the Federal Circuit's ruling in *Teva*. The court of appeals agreed and summarily affirmed the judgment dismissing Apotex's suit. (App. 1a.)

REASONS FOR GRANTING THE WRIT

The Federal Circuit's holding that manufacturers such as Apotex are forbidden from filing a declaratory judgment action, pursuant to the Federal law enacted for this precise purpose, merits this Court's review. That ruling cannot be reconciled with this Court's precedents interpreting the case or controversy requirement of Article III. The question is, moreover, of indisputable importance not only to the generic pharmaceutical industry, but also to the public, which relies so heavily on that industry to provide lower-priced versions of life-saving drugs. Accordingly, this Court should grant certiorari. At the very least, the Court should invite the Solicitor General to file a brief expressing the views of the United States on this critically important issue.

I. The Federal Circuit's Decision Elevates The "Reasonable Apprehension" Test To A Constitutional Standard, In Direct Conflict With This Court's Precedents.

The Federal Circuit's decision impermissibly elevates that court's prudential jurisdictional doctrine (the

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reason. After the Federal Circuit's ruling, Teva had agreed to merge with Ivax, such that Teva might never separately market its own generic Zoloft® product. *See* Pfizer's Br. in Opp'n at 10, 11, 23, 25 (No. 05-48). Teva did not dispute that fact. *See* Teva Reply Br. at 4 (No. 05-48). This Court subsequently denied certiorari. *See Teva Pharms. USA, Inc. v. Pfizer*, 126 S.Ct. 473 (2005).

"reasonable apprehension" requirement) to a "constitutional requirement." *See Teva Pharms.*, 395 F.3d at 1335 (App. 33a). That standard cannot be reconciled with a wall of this Court's precedent, which does not impose such a requirement, but rather holds to the contrary, holding that Article III requires no more than a redressible injury-in-fact traceable to the declaratory judgment defendant's conduct.

It is well-established under this Court's controlling precedent that the only prerequisite to jurisdiction under the Declaratory Judgment Act is an "actual controversy" under Article III, which merely requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Bennett v. Spear,* 520 U.S. 154, 167 (1997); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth,* 300 U.S. 227, 239-40 (1937); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993).

Cardinal Chemical Co. v. Morton International, Inc., for example, addressed the circumstances in which Article III permits a declaratory judgment action with respect to a patent infringement claim. 508 U.S. 83. Recognizing that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy," this Court explained that "[i]n patent litigation, a party may satisfy that burden, and seek a declaratory judgment, even if the patentee has not filed an infringement action." *Id.* at 95. The Court quoted with approval Judge Markey's recognition in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988), that cases such as this present

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act . . . . 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.*

Cardinal Chem., 508 U.S. at 95-96 (quoting *Arrowhead Indus. Water*, 846 F.2d at 734-735) (emphasis added).

Indeed, this Court's seminal ruling "upholding the [declaratory judgment] statute" – *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227 (1937) – arose from an indistinguishable context "in which there was no imminent risk of suit because the potential plaintiff declined to sue." *Teva*, 405 F.3d at 996 (App. 63a) (Dyk, J., dissenting). In *Aetna*, an insurer filed a declaratory judgment action regarding its obligations to the policyholders. Aetna sued precisely because the policyholders had "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability." 300 U.S. at 239. This Court held Article III satisfied in light of the "definite and concrete" dispute relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be

appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 241.[5] The criteria set forth by this Court's precedents are easily satisfied in the recurring factual circumstances of this case.

In listing the '699 patent with the FDA, Pfizer formally took the position that generic competitors were subject to suit for infringement of that patent if they marketed prior to its expiration. Apotex seeks to market its generic product before the '699 patent expires, maintaining that its product would not infringe the '699 patent or that the patent is invalid. Apotex currently is injured by virtue of Pfizer's conduct. As an initial matter, Apotex cannot enter the marketplace immediately upon expiration of the '518 patent because FDA cannot approve Apotex's product until Ivax's 180-day exclusivity expires. Should Ivax delay marketing after the '518 patent expires, Apotex's market entry will be further delayed.

Moreover, the very possibility of debilitating patent liability could further delay Apotex from entering the market. Infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs, such as Zoloft®, would ruin most generic companies. As a result, few generic companies can risk going to market

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[5] Given the statutory command to exercise jurisdiction to the fullest constitutional limits (*see* 35 U.S.C. § 271(e)(5)), the question of whether petitioner's suit satisfies Article III is dispositive of whether it satisfies any statutory or prudential standing requirement. The suggestion of the *Teva* majority that the legislative history supports a narrower reading of the statute, 395 F.3d at 1336-37 (App. 35a-38a), obviously cannot be reconciled with the statutory text. In any event, as discussed in the text, the Federal Circuit's decision is directly contrary to the purposes of the statutory scheme.

before a final judicial resolution of their patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows these companies to continue selling drugs at monopoly prices while generic companies struggle to obtain the certainty that they need to launch free from fear of patent infringement liability.

Not even the Federal Circuit majority in *Teva* doubted that generic manufacturers such as Apotex suffer an "injury" in the factual scenario at issue here. 395 F.3d at 1338 (App. 40a). That court simply deems irrelevant as a matter of law that the competitor "is disadvantaged from a business standpoint" and "finds itself at a competitive disadvantage." *Id.* That view is insupportable, as Judge Mayer recognized, dissenting in *Teva*:

> Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.

395 F.3d at 1343 (App. 49a).

Notably, the Federal Trade Commission strongly concurs. "The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays [generic competitors] from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against [the competitor]." FTC *Teva* En Banc Br. 9. "Absent such a decision," every generic competitor "must

wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that [a competitor] can advance the date of the approval of its product is through this litigation. Absent this action, [the competitor] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." FTC *Teva* Panel Br. 21-22.

The Federal Circuit originally adopted its "reasonable apprehension" test for "pragmatic" reasons (*EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996)) that simply do not apply here. It sought to "protect[] quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead Indus. Water*, 846 F.2d at 736. But "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." FTC *Teva* Panel Br. 13. To the contrary, the Federal Circuit in *Teva* recognized that Pfizer declined to file suit to prevent generic competition, not because of ambivalence about its patent rights. 395 F.3d at 1333-34, 1338 (App. 31a). The reasonable apprehension test is simply "ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." FTC *Teva* Panel Br. 12.[6]

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[6] Conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" also are "useful in identifying questions that merit this Court's attention." *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring). This Court accordingly has reviewed Federal Circuit decisions when "other courts have held or assumed" the contrary. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). It therefore bears noting that, in the period that the regional circuits had jurisdiction over patent appeals, they faithfully adhered to this Court's declaratory judgment precedents. The Eighth and District of Columbia Circuits found a jusiticiable

II. The Federal Circuit's Decision Seriously Undermines Congress's Determination to Enhance Generic Pharmaceutical Competition for The Benefit of the American Public.

The Federal Circuit's error is all the more grave because it effectively nullifies an entire statutory scheme. Congress enacted the declaratory judgment provisions invoked by Apotex in this case for the express purpose of permitting suits, such as Apotex's, to go forward in order to ensure that the American public had access to essential, less-expensive generic equivalents.

Before the 1984 Hatch-Waxman Amendments, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to the FDA. And because such testing can, and often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension. *See generally* Susan Kopp Keyack, *The Drug Price Competition and Patent Term*

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controversy whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one*, a standard met here in light of Pfizer's representation that the '699 patent could be invoked as a basis for patent infringement. *See, e.g., United Christian Scientists v. Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 n.25 (D.C. Cir. 1987); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975). Notably, these circuits accorded weight to the fact that the patentee has previously brought infringement actions. *See Sherwood Med.*, 512 F.2d at 728; *United Christian Scientists*, 829 F.2d at 1158 n.25.

Restoration Act of 1984: Is It a Healthy Long Term Solution?, 21 RUTGERS L.J. 147, 153-54, 160-61, 165 (1989); Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & HEALTH 111, 115-16 (1991/1992).

In 1984 and again in 2003, Congress amended the statute in numerous respects in order to speed generic competition. Congress provided that: (a) a brand-name manufacturer's submission of a patent to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" (21 U.S.C. § 355(b)(1)); (b) the filing of an ANDA claiming patent non-infringement or invalidity constitutes a statutory act of patent infringement (35 U.S.C. § 271(e)(2)(A)); (c) federal courts have jurisdiction over such a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5)); and (d) such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).[7]

Through this scheme, Congress sought to "enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Congress correctly recognized the substantial national interest in getting "generic drugs into the hands of patients at reasonable prices—fast" (*In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), and specifically sought to

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[7] Congress also specifically overturned the Federal Circuit's holding that any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement (*see Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861-63 (Fed. Cir. 1984), *superseded by* 35 U.S.C. § 271(e)(1)), which was a principal source of brand name manufacturers' *de facto* patent term extensions.

ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies" (H.R. CONF. REP. NO. 108-391, at 836 (2003)). To effectuate that goal, Congress enacted the declaratory judgment provisions to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 CONG. REC. S15,746 (Nov. 24, 2003).

The Federal Circuit's excessively restrictive test for recognizing a justiciable case or controversy accordingly will have far-reaching, negative consequences for generic pharmaceutical companies and the American public that depends upon generic companies like Apotex to bring more affordable drugs to market. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. The Federal Circuit's ruling encourages brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." *Teva*, 405 F.3d at 994-95 (App. 59a) (Gajarsa, J., dissenting).

Thus, the Federal Circuit's decision, by misapplying this Court's precedent, cripples generic competition by leaving generic companies like Apotex under a debilitating cloud of patent uncertainty and outright precludes marketing for a substantial period. Consequently, it seriously undermines congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States.

Brand-name manufacturers routinely employ the tactics used by Pfizer in this case to delay competition. A perfect example is Pfizer's conduct with respect to the drug Accupril®, for which Apotex also submitted an ANDA. As in this case, Pfizer asserted its patent against only the first ANDA filer (in that case, Teva). Apotex filed a declaratory judgment action in an effort to obtain patent certainty with respect to its own generic equivalent. A district court dismissed the suit, however, for lack of a case or controversy because Pfizer itself refused to file suit. *See TorPharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004). But when another generic competitor (Ranbaxy) entered the market, exposing itself to massive damages, Pfizer promptly filed suit. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, Case No. 05-cv-00620(DRD) (D.N.J.). While several other companies have FDA approval to begin marketing their own generic Accupril® products, the threat of litigation has significantly delayed generic entry. Thus, brand companies like Pfizer have, in effect, created a new "*de facto*" exclusivity period in direct contravention of Congress's express intent.

The consequences for the American public are substantial. As the Federal Trade Commission advised the Federal Circuit, "declaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that *no* generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." FTC *Teva* Panel Br. 8 n.9 (emphasis added).

The high costs of brand-name prescriptions are a significant barrier in most cases to proper medical treatment for many Americans, particularly the elderly. *See* AARP, *Prescription Drug Costs and the Role of Generic Drugs: Public Opinion Among Americans Aged 45 and Over* 2 (Oct. 1, 2002) ("[N]early one in four Americans 45 and older

(24%) reported *not* being able to afford a prescription drug because no generic version was available."). Because generic drugs are sold for a fraction of the prices of their brand-name counterparts, access to generic pharmaceuticals is "perhaps the single most important route to lower personal and national drug costs during the next decade." Steven Findlay, *Easy Way to Cut Costs of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A.

As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." *Generics: FDA Announces Measures to Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 239; *see also* National Institute for Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002) (suggesting that the "advent" of generic anti-depressant drugs "may help rectify" "a persistent under-diagnosis and under-treatment of depression in the U.S."). The cost savings resulting from the availability of generic drugs is inescapable. Indeed, the substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year, without compromising safety or health.[8] Jennifer S. Haas, *et al.*,

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[8] A recent study published in the ANNALS OF INTERNAL MEDICINE, concluded that "broad generic substitution of outpatient prescription drugs could save approximately $8.8 billion, or approximately 11% of drug expenditures for adults . . . in the United States each year." Jennifer S. Haas, *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000*, 142 ANNALS OF INTERNAL MEDICINE 894 (June 7, 2005); *see also* Food and Drug Administration, *FDA White Paper: New FDA Initiative on "Improving Access to Generic Drugs"* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html

Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000, 142 ANNALS OF INTERNAL MEDICINE 895 (June 7, 2005) (indicating that "[b]road dispensing of generic products would achieve savings without compromising safety," because "[g]eneric drugs are believed to provide therapeutic effects similar to those of their brand-name alternatives"); Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html (recognizing that "Americans need generic drugs more than ever" and that "[b]ringing low-cost generic drug alternatives to consumers more quickly can significantly reduce overall health care costs, and increase access to life saving medicines that are just as safe and effective as their brand-name counterparts").

Thus, the decision of the Federal Circuit will have far-reaching negative effects on the American public, as it inevitably and unnecessarily delays access to these lower-cost generic drugs.

(reporting that the average price of a brand-name drug is $72, compared with $17 for its generic counterpart).

CONCLUSION

The petition for certiorari should be granted. Alternatively, the Court should call for the views of the Solicitor General.

Respectfully submitted,

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