No. 05-1006

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

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

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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. GPhA accordingly has a significant interest in the proper construction of the so-called Hatch-Waxman scheme, which Congress enacted to speed the marketing of generic drugs while, at the same time, protecting the legitimate patent rights of brand companies.

STATEMENT OF THE CASE

I. Background to the Statutory Scheme

In the 1984 Hatch-Waxman Amendments to the federal patent and drug laws, Congress sought to ameliorate two substantial obstacles to the efforts of generic drug manufacturers to compete against brand manufacturers. First, Congress created a streamlined process for FDA approval of generic drug products through which generic manufacturers may submit an Abbreviated New Drug Application (ANDA) demonstrating the bioequivalence of the so-called "pioneer" product and its generic equivalent. 21 U.S.C. § 355(j)(2)(A).

Second, Congress adopted a scheme to expedite the litigation of patent disputes. Generic manufacturers, which seek to compete with brand products already in the marketplace, often face the prospect of patent infringement suits by brand companies. Such suits, if successful, could result in debilitating liability if the generic drug were marketed but

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[1] Pursuant to SUP. CT. R. 37.6, *amicus* GPhA states that, for this Brief, counsel for Apotex slightly revised and updated factually GPhA's *Amicus Curiae* brief previously submitted in support of Teva's petition for *writ of certiorari* in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, no. 05-48 (S. Ct.), and that Apotex contributed financially to the preparation and submission of this Brief. Letters reflecting the consent (or lack of objection) of all parties to the filing of this Brief have been lodged with the Court.

later found to infringe the patent. Thus, as Congress knew, in cases of genuine doubt, generic manufacturers may decline to launch their less-expensive products, even if the brand company's patent claims ultimately would have failed.

Congress thus created a statutory mechanism to permit early resolution of potential patent infringement claims against a new generic drug prior to its marketing. Under Hatch-Waxman, brand manufacturers must identify any patent for which "a claim of patent infringement could reasonably be asserted" against the maker of a generic equivalent. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA publishes that patent information in its "Orange Book." In turn, a generic manufacturer's submission of an ANDA challenging the validity, unenforceability, or infringement of an Orange Book-listed patent constitutes a statutory act of patent infringement, vesting federal courts with subject matter jurisdiction over an infringement suit. 35 U.S.C. § 271(e)(2).

Congress contemplated that these provisions would resolve patent disputes soon after the ANDA is filed. To encourage generic companies to avail themselves of these new statutory provisions, Congress amended the statutory scheme in other ways as well. For example, Congress created an incentive for brand companies to bring a patent infringement claim after learning of the ANDA filing. If a brand company initiates patent litigation within forty-five days of receiving notice of an ANDA applicant's challenge to its patent, FDA must defer approval of the generic product for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

Congress also encouraged generic drug development by providing that the owner of the first ANDA containing a challenge to a listed patent receives a 180-day period of marketing exclusivity against other generic competitors for that drug product. 21 U.S.C. § 355(j)(5)(B)(iv). Specifically, FDA must defer approval of later-filed applications until 180 days after the earlier of two specified dates. *Id.* Of particular relevance to this case is the fact that a later generic applicant can trigger the start of this 180-day period by ob-

taining a judgment declaring the listed patent invalid, unenforceable, or not infringed. *Id.*

The Hatch-Waxman provisions were only a partial success, however. Through various tactics, brand companies could use the exclusivity period granted to first ANDA filers to block later generic competitors from the marketplace for years. Despite the thirty-month stay that would result if a brand company initiated suit within the forty-five day Hatch-Waxman window, brand companies often had a substantial incentive to refrain from instituting litigation before the generic drug was brought to market. A judicial determination could produce a finding of non-infringement that would trigger the start of the 180-day exclusivity period, thereby allowing more generic companies to enter the market sooner. Declining to institute patent litigation also can create a cloud of patent uncertainty that delays generic market entry longer than a patent suit itself.

District courts often have ruled that declaratory judgment actions must be dismissed for failure to satisfy the Federal Circuit's "reasonable apprehension" test. Even though Congress clearly contemplated that generic manufacturers would be permitted to resolve patent claims through a declaratory judgment suit against the patentee, the Federal Circuit, with exclusive jurisdiction over patent appeals, has held that such a suit was impermissible unless the plaintiff itself faced a reasonable apprehension of suit from the patentee. *See, e.g., BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). That rule rested on the court's "pragmatic" concern that merely obtaining a patent should not subject the patentee to litigation. *Id.*

In response to these continuing impediments, Congress enacted further legislation in 2003 "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). As amended, the legislation provides that, if the brand company does not bring suit within the forty-five day Hatch-Waxman period, the generic

competitor may itself institute a declaratory judgment action. 21 U.S.C. § 355(j)(5)(C). Recognizing its power to remove the Federal Circuit's prudential standing barrier, Congress further provided that the district courts would have jurisdiction over such a suit to the fullest "extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

II. The Instant Litigation And Lower Court Rulings

1. This case arises from petitioners Apotex Inc.'s and Apotex Corp.'s (Apotex) intention to market a generic equivalent to respondent Pfizer's antidepressant Zoloft® (sertraline hydrochloride). As is relevant here, Pfizer listed in the Orange Book two patents in connection with Zoloft®. According to Pfizer, one of these patents expires in 2006; the other (known as the '699 patent") expires in 2010.

In 2003, Apotex filed an ANDA for a generic equivalent of Pfizer's Zoloft®. Apotex represented in its ANDA that it intended to begin marketing as soon as Pfizer's first patent (the '518 patent) expired in 2006. Apotex further represented that the '699 patent either would not be infringed or was invalid. Apotex's ANDA submission constituted a technical act of infringement of the '699 patent. However, Pfizer did not sue Apotex. Pfizer knew that its refusal to bring suit would impede and delay competition by Apotex in at least two ways. First, such refusal would create a cloud of patent uncertainty, threatening Apotex with the prospect of massive patent liability if it brought its drug to market before the '699 patent expired in 2010. Second, by avoiding a resolution of the patent dispute, Pfizer prevented FDA from approving Apotex's product until at least 180 days *after* Pfizer's first patent expired in 2006. Pfizer was successfully able to avoid resolving the dispute by entering into a side agreement with another generic manufacturer, Ivax, which filed the first ANDA for sertraline and thus had a right to generic exclusivity for its sertraline product. Pfizer had sued Ivax for patent infringement in response to Ivax's ANDA, but settled in exchange for a share of the revenues from Ivax's sales. Apotex could avoid or limit this additional 180-

day delay, however, if it secured a court judgment that Pfizer's '699 patent was either invalid or not infringed prior to the expiration of Pfizer's first patent. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

2. To remove the cloud of patent uncertainty over its product, and to avoid the delay in FDA approval resulting from the Pfizer/Ivax agreement, Apotex brought its declaratory judgment action against Pfizer. The district court, however, misapplied this Court's precedent and prior Federal Circuit precedent to hold that Apotex's claim was not ripe. (*See* Pet. App. 2a-15a). The district court did not doubt that Apotex was injured by its inability to enter the marketplace based upon a failure to resolve the patent controversy. Indeed, the district court recognized the "gaming of the system" by brand companies. (*Id.* 4a-5a). Nonetheless, the district court concluded 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. (*Id.* 12a-15a).

The Teva Decision

3. Apotex appealed. While that appeal was pending, the Federal Circuit decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (Pet. App. 16a-49a), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005) (Pet. App. 50a-68a), *cert denied*, 126 S. Ct. 473 (2005), which involved the justiciability of another generic manufacturer's declaratory judgment action against Pfizer regarding the same drug product at issue here, sertraline hydrochloride. (Pet. App. 16a-17a). Teva, joined by the AARP and the Federal Trade Commission (FTC) as *amicus curiae*, argued that a justiciable case or controversy existed on these recurring facts.[2] The FTC emphasized the "important role" this case would play "in furthering competitive pharmaceutical markets and in

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[2] FTC's brief (FTC Panel Br.) is available at http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf.

lowering health care cost[s]." (FTC Panel Br. 3). "This issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment action" may be "the *only* means by which a generic drug maker may be able to" bring a competing product to market. (*Id.* (emphasis added)). The FTC explained: "If the district court's decision is upheld, it will enable first generic applicants and brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug." (*Id.* 3-4).

A divided panel of the Federal Circuit nonetheless affirmed the *Teva* lower court decision. (Pet. App. 41a). The panel majority acknowledged this Court's prior holding that the existence of an "actual controversy" sufficient to bring a declaratory judgment action depends on "'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.'" (*Id.* 26a).

Teva's brief demonstrated that there was indeed a concrete controversy between it and Pfizer. For example, by listing its patents in the Orange Book, Pfizer had declared that Zoloft® was protected by the '699 patent, whereas Teva contended that the '699 patent did not preclude its market entry. Pfizer moreover previously had invoked that patent to sue Ivax when Ivax sought to introduce a generic equivalent for Zoloft®. Though Teva's ability to bring its product to market was directly precluded by Pfizer's conduct, Pfizer had refused Teva's request for a covenant not to sue. Despite these undisputed facts, the Federal Circuit concluded that its so-called "reasonable apprehension" test is a constitutional threshold for bringing a declaratory judgment action. (*See* Pet. App. 33a-34a). The court held that a declaratory judgment action is justiciable only if there 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." (*Id.* 27a). Indeed, according to the Federal Circuit, the declaratory judgment plaintiff must "demonstrate that it has a reasonable apprehension of [an] *imminent* suit." (*Id.* 30a).

The panel majority concluded that Teva could not meet this rigorous standard because the very point of Teva's claim was that Pfizer sought to *avoid* a court adjudication of the dispute: "Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination. . . ." (Pet. App. 31a). The majority found it irrelevant that Teva was injured by this state of affairs:

> 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.*

(*Id.* 40a (emphasis added)). The court 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.*).

4. Teva petitioned for rehearing *en banc*, again supported by amicus FTC (FTC En Banc Br.). The petition was denied over the dissenting votes of three judges who issued two dissenting opinions. (Pet. App. 51a). Teva subsequently filed a petition for writ of certiorari with this Court. In its opposition to that petition, Pfizer argued that Teva's claimed controversy "will almost certainly never ripen into any actual dispute in light of its acquisition of Ivax." (Respondent's Br. at 10). The Supreme Court agreed and denied Teva's petition. *Teva*, 126 S. Ct. 473.

The Current Appeal

5. Before the Federal Circuit here, Pfizer argued that Apotex's appeal was controlled by the Federal Circuit's *Teva* ruling. The Federal Circuit agreed, summarily affirming the judgment dismissing Apotex's suit. (Pet. App. 1a).

REASONS FOR GRANTING THE WRIT

Apotex's petition for certiorari should be granted for at least two reasons. First, the Federal Circuit's decision is flatly contrary to this Court's precedents identifying the "case or controversy" required to invoke the jurisdiction of the federal courts. The ruling below moreover conflicts with decisions of other circuits that faithfully apply this Court's decisions. Second, the question also is of indisputable importance. This Court has in the past granted certiorari to review important rulings of the Federal Circuit on questions of patent law, and it should do so here.[3] This case also is an ideal vehicle to resolve the questions presented. Apotex's claim against Pfizer presents two distinct injuries that, in *amicus*'s view, give rise to an Article III case or controversy. Apotex is both (a) precluded from securing FDA approval,

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[3] For recent examples, *see Medimmune, Inc. v. Genentech, Inc.*, 126 S. Ct. 1329 (2006); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 601 (2005); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

and (b) deterred from entering the market, resulting from the prospect of patent liability. By granting the petition, the Court can address in one case whether either or both injuries are sufficient to trigger the jurisdiction of the federal courts.

Certiorari accordingly should be granted. At the very least, the Court should invite the Solicitor General and the Federal Trade Commission to file briefs expressing the views of the United States.

I. The Federal Circuit's Decision Is Contrary To This Court's Precedents Defining The "Case Or Controversy" Required By Article III And Further Conflicts With The Precedent Of Other Circuits.

1. Congress has granted the federal courts jurisdiction to decide declaratory judgment suits brought by generic manufacturers against brand manufacturers to resolve patent claims to the fullest "extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Federal Circuit held that the Constitution prohibits such a suit unless the generic manufacturer "has a reasonable apprehension of *imminent* suit" by the brand-name manufacturer. (Pet App. 30a).

This ruling cannot be reconciled with this Court's precedents. "The 'irreducible constitutional minimum of standing,'" this Court has held, "contains three requirements":

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact"–a harm suffered by the plaintiff that is "concrete" and "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be causation–a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability–a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998) (citations omitted).

The Federal Circuit held that Apotex failed to meet the first standing requirement because the only injury it was willing to recognize—a suit by Pfizer—was insufficiently "imminent." That holding is clearly wrong. This Court's precedents require that the *injury* be "imminent," as opposed to "conjectural" or "hypothetical." There is no requirement that *litigation* filed by the other side must be imminent. Put another way, Article III provides for jurisdiction not merely when there is a "case," but also when there is a "controversy." That requirement is satisfied in these circumstances.

The Federal Circuit's contrary holding is flatly at odds with this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), addressing the circumstances in which Article III of the U.S. Constitution permits a declaratory judgment action with respect to a patent infringement claim. 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." *Cardinal Chem.*, 508 U.S. at 95. In support, this Court quoted with approval Judge Markey's opinion in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988), recognizing 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 (emphasis added). As demonstrated here, the Federal Circuit refuses to heed *Cardinal Chemical*, instead insisting that a declaratory judgment plaintiff have not only a real and immediate controversy with the defendant, but also the prospect of imminent suit.

Outside the patent context, this Court's seminal ruling "upholding the [declaratory judgment] statute" involved, as Judge Dyk explained in his dissenting opinion in *Teva*, a situation precisely analogous to the one here—"one in which there was no imminent risk of suit because the potential plaintiff declined to sue." (Pet. App. 63a (citation omitted)). In *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), the plaintiff insurance company sought a declaration of its obligations to the policyholders. Not only had the policyholders "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability," *Aetna Life,* 300 U.S. at 239, but Aetna sued for the very reason that there was no present prospect of the parties' rights being adjudicated. This Court nonetheless found a sufficient controversy because the case involved a "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 (citations omitted).

Prior to the transfer of exclusive jurisdiction of such questions to the Federal Circuit, the regional circuits faithfully applied this Court's precedents in analogous circum-

stances.[4] The Eighth and District of Columbia Circuits considered whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one, rather than* whether the plaintiff had a reasonable apprehension of an imminent suit. *See, e.g., United Christian Scientists v. Christian Sci. 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). That standard is met here, as Apotex unquestionably faced a reasonable threat of suit given that Pfizer listed the '699 patent in the Orange Book, failed to provide Apotex with any reassurance that it will not sue Apotex or that Apotex's generic will not infringe the '699 patent, and sued Ivax for patent infringement.[5]

Two other circuits similarly applied a less stringent standard than the Federal Circuit's. The Ninth Circuit considers whether "the plaintiff has a real and reasonable apprehension that he will be subject to liability"—a fact-based determination that looks at "[t]he acts of the defendant . . . in view of their likely impact on competition and the risks imposed upon the plaintiff, to determine if the threat perceived by the plaintiff [is] real and reasonable." *Chesebrough-Pond's, Inc. v. Faberge, Inc.*, 666 F.2d 393, 396 (9th Cir.

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[4] This Court's practice of reviewing Federal Circuit decisions when "other courts have held or assumed" the contrary, *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 60 (1998), recognizes that conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" are "useful in identifying questions that merit this Court's attention," *Holmes Group*, 535 U.S. at 839 (Stevens, J., concurring).

[5] In reviewing the totality of the circumstances in connection with a reasonable apprehension analysis, the Eighth and District of Columbia Circuits have accorded weight to the fact that the patentee has previously brought infringement actions. *See United Christian Scientists*, 829 F.2d at 1158 n.25 (noting that "prior record of infringement charges against the declaratory plaintiff or others similarly situated" is one of the factors "which courts have regularly recognized as buttressing a reasonable apprehension"); *Sherwood Med.*, 512 F.2d at 728 (recognizing that patentee's *entire* course of conduct, including past litigation, supported a "reasonable apprehension" of impending litigation).

1982). And while the First Circuit—which considered the question in the context of a dispute over which it had jurisdiction under World Trade Organization procedures—expressly holds that the "reasonable apprehension of suit" standard is not the only way to establish Article III jurisdiction unless "the only controversy surrounds a potential, future lawsuit," that court holds that, even in the absence of such a potential suit, the facts of a particular case may demonstrate that such a controversy exists. *See Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001) (citations omitted).

2. It cannot be seriously argued that Apotex's declaratory judgment complaint fails to state an Article III case or controversy under this Court's precedents and the standard articulated by other circuits based on such precedent. There is a concrete legal controversy between Apotex and Pfizer with respect to whether Apotex's generic product infringes Pfizer's patent. Pfizer's listing of the '699 patent in the Orange Book constituted a representation by it that "a claim of patent infringement could reasonably be asserted" against a generic equivalent on the basis of that patent. 21 U.S.C. §§ 355(b)(1), (c)(2). Apotex has alleged that it intends to market a drug that, according to the Orange-Book listing, Pfizer believes will violate its patent. Under the federal patent laws, Apotex's filing of an ANDA challenging the validity or infringement of that patent constitutes a technical act of patent infringement as matter of law. 35 U.S.C. § 271(e)(2). Pfizer has further refused to acknowledge that Apotex's product is non-infringing. In these circumstances, only a suit by Apotex can resolve the controversy.

Nor is there any serious dispute that Apotex has suffered an "injury." Even the Federal Circuit did not doubt in the slightest that Teva had suffered an "injury" in similar circumstances. (Pet. App. 39a-40a). Instead, the *Teva* court deemed the fact that a generic manufacturer "is disadvantaged from a business standpoint" as irrelevant as a matter of law. (*Id.* 40a). Apotex is faced with this very situation here.

The legal dispute that Apotex seeks to resolve has at least two definite, adverse consequences for Apotex that would be remedied by a judgment in its favor—and, indeed, can *only* be remedied by such a judgment. First, Apotex is deterred by the prospect of devastating infringement liability from entering the marketplace. Manufacturers in Apotex's position frequently have massive investments tied up in the development of their generic equivalents by the time that they submit an ANDA. As Judge Mayer recognized in his *Teva* dissent, ANDA applicants such as Apotex "suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic product free from infringement allegations." (Pet. App. 49a). "[D]eclaratory 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 Panel Br. 8 n.9 (citation omitted)).

Second, even if Apotex wanted to market its drug before receiving patent certainty, the FDA *cannot* approve Apotex's generic equivalent for at least 180 days after the expiration of Pfizer's first patent, unless Apotex secures an earlier favorable patent judgment. (*See* FTC Panel Br. 2). Thus, "[t]he controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays [Apotex] from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against [Apotex]." (FTC En Banc Br. 9). "Absent such a decision, [Apotex] (and every other ANDA applicant) instead 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 [Apotex] can advance the date of the approval of its product is through this litigation. Absent this action, [Apotex] suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." (FTC Panel Br. 21-22).

3. The Federal Circuit's holding that Apotex nonetheless fails to state a justiciable controversy because it does not face an "*imminent* suit" from Pfizer is unsupportable. (*See* Pet. App. 30a). The "pragmatic" concern that gave rise to the Federal Circuit's reasonable apprehension test is completely missing here. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811-12 (Fed. Cir. 1996). That requirement was adopted to "protect[] quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead*, 846 F.2d at 736 (citation omitted). The prudential standing rule thereby seeks "to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978 (citation omitted). The rule is "but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law." (Pet. App. 52a (Gajarsa, J., dissenting)). But in this context, "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." (FTC Panel Br. 13). To the contrary, as Judge Mayer recognized in his *Teva* dissent, "[b]y listing its patent [in the Orange Book], Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires." (*Id.* 46a). Both the district court and the court of appeals recognized that Pfizer—like other brand-name manufacturers in its position—declined to file suit not because of ambivalence about its patent rights, but instead to prevent generic competition. (*See id.* 4a-5a, 40a). Any doubt is resolved by the facts that Pfizer sued Ivax on an indistinguishable claim and refused to grant Apotex any reassurance that Pfizer will not sue Apotex for infringement.

Thus, the Federal Circuit's odd rule that litigation must be imminent "is 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 Panel Br. 12). The prudential interest in limiting the burdens of litigation on patent holders is simply overborne in this circumstance.

But even if it otherwise applied, the Federal Circuit's prudential standing rule did not survive Congress's enactment of a specific directive that federal courts shall exercise jurisdiction over suits such as this to the fullest extent consistent with the Constitution. *See* 35 U.S.C. § 271(e)(5); *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997) (recognizing that Congress may eliminate prudential standing rules by statute).

II. The Question Presented Is Vitally Important To Pharmaceutical Competition.

Apotex's petition also should be granted because it presents a question of fundamental importance to competition in the pharmaceutical industry and, accordingly, to the American public that relies so heavily on lower-priced generic drugs to combat the skyrocketing costs of healthcare.

1. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic drug companies to resolve patent disputes with brand-name manufacturers. The decision provides a roadmap for brand-name manufacturers to preclude litigation of all such disputes. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." (Pet. App. 59a (Gajarsa, J., dissenting)).

As this Court has previously recognized, Congress enacted those provisions of the Hatch-Waxman scheme at issue here "to enable new drugs to be marketed more cheaply and quickly . . . ." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). "Quite obviously, the purpose of these provisions] is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Id.* at 678. And just as the "scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement" (*id.*), it "will not work" if the patent holder can prevent generic manufacturers from establishing in court that there has been no infringement on the pioneer's patents.

The FTC concurs that "[d]eclaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime," (FTC Panel Br. 12), and, as a consequence, "further[] competitive pharmaceutical markets and in lowering health care costs," (FTC En Banc Br. 2). Indeed, the FTC concludes that "even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because competition among generic manufacturers has a strong impact on the price of a drug." (FTC Panel Br. 8).

Amicus GPhA has surveyed its membership to determine the significance of the very question presented here. The responses confirm that the Federal Circuit's decision fundamentally affects competition throughout the pharmaceutical industry. The survey conclusively established two facts: (i) the FTC and the dissenting judges in *Teva* correctly concluded that these circumstances present a concrete controversy; and (ii) the number of drugs affected by the decision is large and constantly growing.

GPhA's members report that they regularly defer entering the market until they can litigate the question of patent infringement to at least a district court judgment.[6] By not bringing suit, brand companies perpetuate paralyzing uncertainty that allows them to continue selling their branded

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[6] To cite just a few examples:

- Eon Labs launched its equivalent to Sporanox® only after a favorable district court judgment. *Janssen Pharm. N.V. v. Eon Labs Mfg., Inc.*, 374 F. Supp. 2d 263 (E.D.N.Y. 2004).
- Geneva launched its equivalent to Augmentin® only after a favorable district court judgment; other manufacturers then followed suit. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 213 F. Supp. 2d 597 (E.D. Va. 2002), *aff'd*, 349 F.3d 1373 (Fed. Cir. 2003).
- Barr Labs launched its equivalent to Mircette® only after a favorable district court judgment. *Bio-Technology Gen. Corp. v. Duramed Pharms., Inc.*, 174 F. Supp. 2d 229, 232 (D.N.J. 2001).
- Conversely, Eon Labs has been precluded from litigating with respect to its generic equivalent to Pfizer's Accupril® and has not entered the market despite having final approval.

drugs at monopoly prices. The decision below is particularly pernicious because it is the drugs that the public most frequently uses—and that give rise to the greatest possible infringement liability—that will suffer reduced competition. Infringement damages for blockbuster drugs such as Zoloft® (generating annual revenues for Pfizer well in excess of $2 billion) would ruin most generic companies.

GPhA's members also report that the ruling below would have a sweeping effect. Generic manufacturers regularly seek to market generic equivalents and represent in their ANDAs that the patents listed in connection with the innovator drug are either invalid or will not be infringed. The most recent data published by the FDA indicates that generic manufacturers have filed such ANDA certifications for over 300 drugs. *See* http://www.fda.gov/cder/ogd/ppiv.htm (last visited Mar. 29, 2006). More than seventy of these certifications were submitted in the last two-and-a-half years alone. *Id.* Many of those drugs are likely to present patent issues that ought to be resolved promptly but, under the Federal Circuit's ruling, cannot be.

The following examples illustrate the broad sweeping effect of the *Teva* ruling:

- The ruling does not merely affect Apotex with respect to Zoloft®. In addition to Apotex and Teva, Dr. Reddy's filed an ANDA seeking to market generic Zoloft® products and brought a similar declaratory judgment action. That action was dismissed on the same ground as the Federal Circuit's ruling here. *See Dr. Reddy's Labs., Ltd. v. Pfizer Inc.*, No. Civ.A.03-CV-726(JAP), 2003 WL 21638254 (D.N.J. July 8, 2003).

- The ruling also affects numerous other drugs. For example, generic manufacturers have attempted to litigate the patent validity/non-infringement of generic equivalents to Pfizer's Accupril® (which generates nearly $600 million in annual U.S. sales). More specifically, two generic manufacturers that filed ANDAs for Accupril® sought a declaratory judgment when Pfizer failed to sue. Those cases were

dismissed on the same rationale as the *Teva* decision. *Tor-Pharm, Inc. v. Pfizer Inc.*, No. Civ.03-990-SLR, 2004 WL 1465756 (D. Del. June 28, 2004), *vacated and remanded by* 125 Fed. Appx. 987 (Fed. Cir. 2005)[7]; *Mut. Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004).

- Teva and Mylan Laboratories submitted ANDAs with respect to Merck & Co.'s Proscar®. Merck did not file suit against either. Relying on the *Teva* decision, the district court dismissed Mylan's declaratory judgment action. *Mylan Pharms. Inc. v. Merck & Co.*, No. Civ. 1:05-cv-1416, 2005 WL 2850137 (M.D. Pa. Oct. 28, 2005).

2. By substantially impeding generic competition, the Federal Circuit's ruling will directly injure consumers and the public health. Because generic drugs are generally sold for a fraction of the prices of their brand-name counterparts, the substitution of generic drugs for brand-name drugs results in billions of dollars in savings each year.[8] A one-percent increase in the substitution of generic drugs for brand-name drugs could result in a savings of up to $2 billion per year, while the widespread substitution of generic drugs for brand-name drugs whenever possible could save U.S. consumers as much as $17 billion per year. Dep't of Health & Human Services Task Force on Drug Importation,

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[7] Apotex appealed that district court decision. Upon learning that the panel in the case included two judges (Mayer and Gajarsa) who had in previous cases expressed the view that a case or controversy exists in these circumstances, and before the denial of *en banc* review in *Teva*, Pfizer granted Apotex a covenant not to sue, rendering Apotex's appeal moot. *See Apotex Inc. v. Pfizer Inc.*, 125 Fed. Appx. 987 (2005).

[8] *See* 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 (reporting that average price of a brand-name drug is $72, compared with $17 for its generic counterpart); Statement of the FTC on *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*, Before the Committee on the Judiciary of the United States Senate (May 24, 2001), *available at* http://www.ftc.gov/os/2001/05/pharmstmy.htm (estimating that consumers saved $8 to $10 billion in 1994 by substituting generics for brand-names).

REPORT ON PRESCRIPTION DRUG IMPORTATION 68 (Dec. 2004), *available at* http://www.hhs.gov/importtask force/Report1220.pdf; Steven Findlay, *Easy Way To Cut Costs Of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A.

Access to generic pharmaceuticals thus is "perhaps the single most important route to lower personal and national drug costs during the next decade." Findlay, *supra*. Indeed, the cost savings created by generic pharmaceuticals translates directly into improved public health and, accordingly, lives saved. 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 231; *see also* The National Institute For Health Care Management (NIHCM), *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace* 19 (June 2002) ("[t]he advent of [the generic equivalent of the anti-depressant Prozac]" may help rectify the "persistent under-diagnosis and under-treatment of depression in the U.S."), *available at* http://www.nihcm.org/finalweb/GenericsPrimer.pdf.

High prescription costs are a significant—and at times, insuperable—barrier to proper treatment for many Americans, particularly the elderly. *See Generics Key To Cost Control*, UPI, May 19, 2005 ("the No. 1 reason why patients do not take their medicine is because it is too expensive"); AARP, *Prescription Drug Costs And The Role Of Generic Drugs: Public Opinion Among American Aged 45 and Older* 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."), *available at* http://assets.aarp.org/rgcenter/health/rxgeneric. pdf.

CONCLUSION

The petition for a writ of certiorari should be granted or, at a minimum, the Court should invite the Solicitor General and the Federal Trade Commission to file briefs expressing the views of the United States.

Respectfully submitted,

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