No. 05- 1006

IN THE

Supreme Court of the United States

APOTEX INC. AND APOTEX CORP.,

Petitioners,

v.

PFIZER INC.,

Respondent.

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

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the court below properly determined, on the particular factual record of this declaratory-judgment action, that there was not a ripe Article III case or controversy for it to adjudicate, particularly given that the declaratory-judgment plaintiff could not yet market the potentially infringing product regardless of the outcome, and given that the plaintiff acknowledged that the declaratory-judgment defendant had no current interest in asserting its patent rights against the plaintiff.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer") states that it has no parent and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

TABLE OF AUTHORITIES
(Continued)

Page

Federal Statutes

TABLE OF AUTHORITIES
(Continued)

Page

Legislative History

Miscellaneous

RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

In this action, petitioners Apotex Inc. and Apotex Corp. (collectively, "Apotex") seek an advisory opinion on whether a generic pharmaceutical that they may attempt to market at some point in the future, but for which they concededly will not seek FDA approval until at least July 2006, infringes a patent that they themselves allege respondent Pfizer has no present interest in asserting against Apotex. Summarily affirming the district court, the Federal Circuit properly declined the invitation to embark on such a hypothetical, speculative inquiry in light of the Article III requirement of an actual and concrete "Case[]" or "Controvers[y]." Such a routine justiciability determination, based on the specific factual circumstances of this case, and involving a statutory scheme that has since been amended to alter the analysis fundamentally in future cases, does not warrant this Court's review.

A. The Statutory Scheme Governing Expedited FDA Approval of Generic Pharmaceuticals.

1. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, manufacturers of both innovative and generic pharmaceuticals must follow procedures for Food and Drug Administration ("FDA") approval of a drug, which include the filing of a New Drug Application ("NDA"). *Id.* § 355(a). In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282), (commonly referred to as the Hatch-Waxman statute), however, Congress alternatively provided for special, expedited procedures for the introduction of generic pharmaceuticals into the marketplace. Reflecting a balance between the policies of creating incentives for innovating new pharmaceuticals and allowing the prompt introduction of less-expensive generic

products into the marketplace, the expedited Hatch-Waxman procedures allow manufacturers of generic pharmaceuticals that are identical and bioequivalent to drugs previously approved by the FDA to obtain approval by filing an Abbreviated New Drug Application ("ANDA"), rather than a full NDA. 21 U.S.C. § 355(j).

The process for approval of such a tag-along ANDA application builds off of the filing of the earlier, completed NDA for a new pharmaceutical product. In conjunction with the initial NDA filing, the NDA applicant is required to provide to the FDA a list of all patents "claim[ing] the drug for which the applicant submitted the application" and "with respect to which a claim of patent infringement could reasonably be asserted." *Id.* § 355(b)(1); *see also id.* § 355(c)(2). The FDA publishes these patent listings in an appendix to the "Orange Book," *Approved Drug Products With Therapeutic Equivalence Evaluations*, *available at* http://www.fda.gov/cder/ob/default.htm (last visited Apr. 6, 2006).

An ANDA filer for FDA approval may, upon demonstrating the identity and bioequivalence of its product with the prior NDA product, rely upon the earlier drug's safety and efficacy studies. 21 U.S.C. § 355(j)(2)(A); Pet. App. 4a. Accompanying such an ANDA filing, a generic applicant must make one of four possible certifications with respect to every patent listed in the Orange Book under the NDA on which the ANDA is premised. A "paragraph I" certification states that required patent information was not filed by the NDA holder with the FDA. A "paragraph II" certification indicates that the patent in question has expired. A "paragraph III" certification states that the patent will expire on a particular date in the future, in which case the FDA cannot approve the ANDA until after that expiration date has passed. And a "paragraph IV" certification states that "the patent is invalid or will not be infringed by . . . the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

Under the Hatch-Waxman Act, while steps necessary to prepare an ANDA do not constitute infringement of an Orange Book patent (even if those acts might otherwise be infringing), the actual filing of an ANDA containing a paragraph IV certification is deemed a statutory act of patent infringement. 35 U.S.C. § 271(e)(2). Moreover, an applicant's filing of an ANDA incorporating a paragraph IV certification starts a 45-day period during which the patentee may sue the ANDA applicant for this statutory infringement, and during which the ANDA applicant may not bring a declaratory-judgment action with regard to the patent that was the subject of the certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues for infringement during this period, the FDA may not approve the ANDA for thirty months, unless the lawsuit is resolved in favor of the ANDA applicant. *Id.* If the 45-day period expires without the patentee bringing suit, the FDA may approve the ANDA. *Id.*

Under the statute, the first ANDA applicant to file a paragraph IV certification receives the benefit of a 180-day exclusivity period during which the FDA may not approve any other paragraph IV ANDAs based upon the same NDA. *Id.* § 355(j)(5)(B)(iv). Under the statutory regime applicable to this case (but that has since been amended, as discussed below), the 180-day exclusivity period began to run upon the earlier of two events: The date when the ANDA product was first commercially marketed, or "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv).

2. In 2003, however, Congress amended this statutory scheme in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"). The Medicare Amendments make several pertinent changes to the ANDA approval process.

Most significantly, the Medicare Amendments revise the provisions governing the 180-day exclusivity period for a first ANDA filer in all ANDAs filed after December 8, 2003. The new provisions change the statute so that, rather than have a court-decision alternative as a possible means to begin the 180-day exclusivity period, the 180-day exclusivity period begins to run only on the date of first commercial marketing, 21 U.S.C. § 355(j)(5)(B)(iv), subject to a forfeiture of the exclusivity under six circumstances: (1) if the first applicant fails timely to market the pharmaceutical; (2) if the first applicant withdraws its ANDA; (3) if the first applicant withdraws its paragraph IV certification; (4) if the first applicant fails to obtain tentative approval within specified time periods; (5) if the first applicant enters into an agreement found by the Federal Trade Commission ("FTC") or a court to violate the antitrust laws; or (6) if all patents subject to paragraph IV certifications expire. *Id.* § 355(j)(5)(D). Thus, while a court judgment of invalidity or non-infringement can factor into the exclusivity analysis, it does so only in an entirely different way from the pre-2003 regime at issue in this case — specifically, only as a subsidiary component of the "failure to market" forfeiture analysis. *Id.* § 355(j)(5)(D)(i)(I)(aa). These new criteria for starting the 180 days and the forfeiture provisions (with the exception of the collusive agreement forfeiture provision, which is not at issue here) apply only prospectively to ANDAs filed after December 8, 2003, and thus do not apply to this case. *See* Pet. App. 6a (Ivax ANDA filed in 1999), 7a (Apotex ANDA filed on October 27, 2003).

The Medicare Amendments also impose a new requirement upon ANDA applicants who file declaratory-judgment actions regarding Orange Book patents after the expiration of the 45-day period. Specifically, they require that such ANDA applicants offer confidential access to the ANDA materials to allow the patentee or NDA holder to evaluate issues pertaining to infringement. 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). The Medicare Amendments

also state that, after the 45-day period, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

B. The FDA's Approval of Zoloft®, The Subsequent ANDAs, And The Litigation Below

1. Pfizer manufactures and sells Zoloft®, a pharmaceutical for treating certain mood and anxiety disorders. The active ingredient in Zoloft® is sertraline hydrochloride, which acts by inhibiting the uptake of serotonin in the brain. In obtaining its NDA for this compound, Pfizer filed with the FDA a listing of patents covering Zoloft® or a method of use for Zoloft®, and the FDA published these patents in the Orange Book. Among these patents are United States Patent No. 4,356,518 (the "'518 patent"), which claims the compound sertraline hydrochloride, and United States Patent No. 5,248,699 (the "'699 patent"), which claims a particular polymorphic form of sertraline hydrochloride. Pet. App. 6a.

In 1999, the predecessor to Ivax Pharmaceuticals, Inc. ("Ivax") notified Pfizer that it had filed an ANDA seeking FDA approval to market generic sertraline hydrochloride tablets. In that ANDA, Ivax filed a paragraph III certification with regard to the '518 patent, and thus sought approval for its generic product only beginning after the expiration of that patent, which (as adjusted by the FDA for six months due to Pfizer's performance of requested pediatric studies) will not occur until June 30, 2006. Ivax also filed a paragraph IV certification (claiming invalidity or non-infringement) with regard to the '699 patent. This latter patent will not expire until September 28, 2010, but Ivax's paragraph IV certification meant Ivax was seeking approval before that second patent expires. Pet. App. 6a.

Because Ivax was the first generic manufacturer to file a paragraph IV certification, no subsequent generic applicants can obtain approval for their ANDAs until the expiration of the 180-day period provided by the statute. Under the pre-2003 Hatch-Waxman regime applicable at that time, the 180-day "exclusivity" period would commence from the earlier of Ivax's first commercial marketing of its generic product or a final, non-appealable court decision of non-infringement or invalidity with respect to the '699 patent. 21 U.S.C. § 355(j)(5)(B)(iv).

Within forty-five days after receipt of Ivax's notice, Pfizer sued Ivax, *inter alia*, for infringing the '699 patent. In May 2002, Pfizer and Ivax settled the action. In doing so, Pfizer granted Ivax a license to the '699 patent upon approval of Ivax's generic product by the FDA after the '518 patent (with pediatric exclusivity) expires on June 30, 2006. Pet. App. 6a.

On October 27, 2003, after Pfizer and Ivax had settled Pfizer's infringement lawsuit, Apotex filed an ANDA seeking approval to market generic sertraline hydrochloride tablets. Pet. App. 7a. Like Ivax, Apotex filed a paragraph III certification with respect to the '518 patent, thereby deferring its request for FDA approval until after June 30, 2006, and a paragraph IV certification with regard to the '699 patent. Pfizer did not bring suit against Apotex within forty-five days after receiving its ANDA notice, and made no threats of suit or otherwise engaged in any conduct indicating that it might sue Apotex. Consequently, the '699 patent is not an obstacle to the FDA's approval of Apotex's ANDA, which the FDA can approve immediately after the expiration of the period created by Apotex's own paragraph III certification and the expiration of the 180-day exclusivity period enjoyed by Ivax for being the first paragraph IV filer. 21 U.S.C. § 355(j)(5)(B)(ii), (iv).

2. On April 1, 2004, Apotex sued Pfizer, seeking a declaratory judgment that Apotex's proposed generic

product would not infringe the '699 patent and that claims of the '699 patent are invalid. Pet. App. 7a. Pfizer moved to dismiss the complaint for lack of subject matter jurisdiction and, on January 3, 2005, the district court granted Pfizer's motion. Pet. App. 8a.

The district court noted that there is jurisdiction under the Declaratory Judgment Act only where there is "an actual case or controversy" between the parties. Pet. App. 8a. Applying a test previously announced by the Federal Circuit for examining the presence of a constitutional case or controversy in the patent context, the district court found that there must be some "present activity which could constitute infringement," and also "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit." Pet. App. 9a (internal quotation marks omitted). The district court rejected Apotex's argument that this "reasonable apprehension" test had been abrogated by the Medicare Amendments, Pet. App. 10a-12a, noting that the test embodies "constitutional limits of an Article III court's jurisdiction in anticipatory patent infringement declaratory judgment actions," Pet. App. 11a, and that the legislative history of the Medicare Amendments expressly indicates a congressional intent for the continued application of the test, Pet. App. 11a-12a.

Applying the "reasonable apprehension" test to this case, the district court found the infringing-activity requirement satisfied. Pet. App. 12a. The district court nonetheless found that there was no conduct by Pfizer creating any reasonable apprehension of an infringement suit. Noting that there need not be any "explicitly threatened suit" to give rise to a reasonable apprehension, the district court "consider[ed] the totality of the circumstances" in assessing that question. Pet. App. 13a.

The district court considered several factors that Apotex claimed gave rise to a reasonable apprehension of a lawsuit

against it. The district court concluded that Pfizer's mere listing of the '699 patent in the Orange Book did not create any reasonable apprehension that Pfizer would sue Apotex, noting that "[a]ccording to the plain language of the law, an Orange Book listing represents merely that, in certain circumstances, an infringement claim 'could' be asserted, but not that one will be asserted," and that it thus "does not suggest that a suit is expected or even likely." Pet. App. 13a. Moreover, the district court observed that "[a]n Orange Book listing is directed to the FDA, not any company in particular, and is submitted as a necessary element of the drug application." *Id.*

The district court also rejected Apotex's argument that Pfizer's separate decision to sue Ivax gave rise to a reasonable apprehension that it would also sue Apotex. The district court concluded that the decision whether to sue Ivax involved different strategic considerations and that, in any event, "Pfizer ha[d] not sued any of the other ANDA applicants." Pet. App. 14a.

The district court next considered Pfizer's more general "history of litigation." *Id.* The district court held that unrelated prior litigation does not create a reasonable apprehension of suit against Apotex in the absence of "ongoing litigation between the parties over a series of closely related patents involving the same technology." *Id.* The district court noted that "[c]ompanies that profit largely from research and development will frequently find themselves involved in patent infringement litigation; what creates a reasonable apprehension of suit in any given case is a relationship between that case and some prior litigation." Pet. App. 14a-15a. Because Apotex alleged no such connection with Pfizer's prior litigation, there was no ground for a reasonable apprehension of a lawsuit against Apotex here. *Id.*

Finally, the district court held that "Pfizer's refusal to acknowledge [Apotex's] non-infringement" did not create

any reasonable apprehension of suit by Pfizer. The court noted that Apotex offered no explanation for its contention that "this behavior [wa]s threatening," and found that "[a]t most, Pfizer's refusal is ambiguous; it does not affirmatively show an intent to sue." Pet. App. 15a.

Finding that the totality of the circumstances did not support any reasonable apprehension on the part of Apotex that Pfizer would sue it, the district court held that there was no jurisdiction to support Apotex's declaratory judgment action. The district court therefore granted Pfizer's motion to dismiss. *Id.*

3. After the district court's decision in this case issued, the Federal Circuit decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir.), Pet. App. 16a-49a, *reh'g denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005). In *Teva*, the Federal Circuit held that a similarly situated generic manufacturer could not maintain a declaratory judgment action against Pfizer with respect to the Zoloft® patents. Like the district court in this case, the *Teva* panel majority applied the "two-part inquiry" requiring both present infringing activity and facts supporting "a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." Pet App. 27a. Evaluating "the totality of the circumstances," Pet. App. 30a (internal quotation marks omitted), the panel majority there similarly found no case or controversy supporting Teva's declaratory-judgment action on the particular facts of that case. Teva petitioned this Court for a writ of certiorari, and this Court denied certiorari.

4. On December 12, 2005, the Federal Circuit affirmed the district court's decision in this case by a summary per curiam disposition. Pet. App. 1a.

REASONS FOR DENYING THE PETITION

The petition for a writ of certiorari should be denied. It raises no important or recurring issue warranting this Court's review; on the contrary, the decision below is entirely fact-

bound, and because of amendments to the key provisions of the statute, the concern expressed by Apotex has been abrogated by amendments to the operative ANDA regime in cases like this one. Further, the decision below is entirely consistent with this Court's decisions and the decisions of other courts. Finally, the decision below is correct on the merits; the petition's contrary argument rests on a misstatement of both the applicable law and the grounds for the decision below.

I. THE PETITION RAISES NO IMPORTANT OR RECURRING ISSUE WARRANTING THIS COURT'S REVIEW.

At the outset, it should be emphasized that the petition raises no important or recurring issue that could possibly warrant this Court's review. Under this Court's rules, the Court will expend its limited resources to review a case only where there are "compelling reasons" for doing so, including "important question[s] of federal law." Supreme Court Rule 10, 10(c). This requirement of importance of an issue is not satisfied, and a case is unsuitable for review by this Court, where the issue raised in the petition is unlikely to recur outside the case immediately under review. For example, it has been explained that, where intervening amendments to a statutory scheme diminish the likelihood of recurrence of the issue raised in a certiorari petition, an issue is not worthy of review. *See, e.g.*, John M. Harlan, *Some Aspects of the Judicial Process in the Supreme Court of the United States*, 33 AUSTRALIAN L.J. 108 (1959) (noting that review is inappropriate where the issue "is not apt to have continuing legal consequences, as where a statute which has given rise to conflicting interpretations has been repealed or amended"). Similarly, where an issue is narrowly fact-bound, it is not an appropriate candidate for review by this Court. *See, e.g.*, *Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955) (noting that issue should be "beyond the academic or the episodic"). For both of these reasons, the petition here does not warrant review.

First, intervening statutory amendments have fundamentally altered the relevant statutory analysis. They have replaced the procedures governing the exclusivity period in cases involving ANDAs filed after December 8, 2003.

The petition claims that the Pfizer/Ivax settlement created an incentive for Pfizer not to initiate litigation against subsequent ANDA applicants filing paragraph IV certifications, because doing so could theoretically lead to an "adverse court judgment" that, under the extant statutory regime, would cause the exclusivity period to begin running before Ivax began to market its generic pharmaceutical. The petition argues that "the failure to secure a court judgment of non-infringement or invalidity precluded Apotex" from causing the Ivax exclusivity period to start running "until *at least* 180 days after the expiration of the '518 patent." Pet. 4. Apotex asserts that the decision below "encourages brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs." Pet. 16. This was also the issue that concerned the panel and en banc dissenters in the Federal Circuit in the *Teva* case. *See* Pet. App. 46a-47a (Mayer, J., dissenting) (claiming a "cognizable injury" based upon "brand-name firm[s] forego[ing] suing subsequent ANDA applicants" to avoid starting the 180-day period); Pet. App. 57a (Gajarsa, J., dissenting) (claiming that Pfizer "insulated itself from any judicial determination" during the 180-day period); Pet. App. 67a (Dyk, J., dissenting) (finding a controversy because "Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity").

That concern will not arise, however, in future cases in light of the recent Medicare Amendments. As explained above (*supra* at 4), the Medicare Amendments replaced the alternative "court decision" means of starting the 180-day period running with several exclusivity "forfeiture"

provisions, under which a court decision regarding infringement or validity plays an entirely different and substantially more limited role. Indeed, under the Medicare Amendments, an ANDA applicant must have "received tentative approval" for its generic drug in order for an adverse court judgment to enter the analysis at all. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Therefore, a party in Apotex's position (*i.e.*, a party who like Apotex has never received tentative approval for its generic drug) could not make use of any court judgment of invalidity or non-infringement to cause forfeiture of the exclusivity period even if it obtained such a judgment. In other words, as amended, the statute no longer incorporates a simple "adverse judgment" starting point like the one at issue in this case, and the concerns asserted by the petition do not even apply to future cases of this type under the amended statute. In these circumstances, where the operative provision of the statute at issue "has been . . . amended" in a way that will radically alter the issue in future cases and prevent it from arising at all in cases like this one, certiorari review is not appropriate, because the issue raised in the petition "is not apt to have continuing legal consequences." Harlan, *supra*, 33 AUSTRALIAN L.J. at 108.

Second, even under the pre-amendments statutory regime applicable to this case, the petition raises no issue of general significance, because it arises only in a narrowly fact-intensive posture. The Federal Circuit here simply summarily affirmed the district court, and the district court did not purport to pronounce any new rule of justiciability, much less a rule of sweeping application. Rather, the court applied a longstanding test for justiciability, Pet. App. 9a-10a, and made clear that its application of that test was limited to the particular "totality of the circumstances" in the present case, Pet. App. 10a (internal quotation marks omitted); *accord id.* (considering "the full range of the defendant's conduct"); Pet. App. 13a ("consider[ing] the totality of the circumstances"). Such a decision, summarily

affirmed by the appellate court, is plainly not important enough to merit this Court's review.

Specifically, the question in this case arises in, and rests on, a quite unusual combination of independent predicate facts:

- The patentee must have two or more Orange Book patents relating to the NDA product in question.
- These patents must expire at significantly different times.
- There must be at least two prospective generic entrants into the market.
- The prospective generic entrants must file paragraph III certifications with respect to the earlier-expiring patent — thus deferring the onset of both the exclusivity period and the second entrant's attempt to market its generic product — and they must also make paragraph IV certifications with respect to the later-expiring patent.
- The patentee must settle the dispute over the later-expiring patent with the first generic entrant on terms granting it a license.
- The patentee must exhibit no conduct indicating any intention of suing the second generic entrant for infringement based upon its ANDA filing.

It was on these specific and unique facts that the district court below held that, in the "totality of the circumstances," Pet. App. 13a, no ripe case or controversy existed for adjudication. The district court expressly disclaimed reliance on any categorical rules and instead looked to the totality of the evidence to determine whether there existed a controversy of sufficient immediacy to satisfy the justiciability requirements of Article III. The Federal Circuit merely summarily affirmed that fact-bound decision. Moreover, the Federal Circuit has elsewhere clarified that "the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of

an actual case or controversy has been met." Pet. App. 34a. Noting that Apotex had made a Paragraph III declaration with respect to the '518 patent, thus disclaiming any intent to market its generic product until at least June 2006, Pet. App. 7a, and that Pfizer has shown no intent to enforce its patent rights before that time, Pet. 12a, the district court here concluded that there was no current "actual controversy" between the parties, *id.*

In short, the decision below announced no broad or new principle of law and rested upon a fact-bound evaluation of the unusual record in this case. Accordingly, the decision below does not rise "beyond the academic or the episodic," and does not warrant consuming this Court's limited resources to review. *Rice*, 349 U.S. at 74.

II. THE DECISION BELOW IS CONSISTENT WITH THIS COURT'S DECISIONS AND CREATES NO SPLIT AMONG THE CIRCUITS.

Nor is review warranted to resolve any conflict between the decision below and either the decisions of this Court or the decisions of other courts of appeals. The petition errs in suggesting that any such conflict exists. Pet. 8-13.

1. The district court's reliance on and application of the "reasonable apprehension" standard, and the Federal Circuit's summary affirmance of that decision, are fully supported by this Court's cases. That standard distinguishes ripe, justiciable declaratory-judgment actions from those that are not ripe and immediate.

a. As this Court has long held, in order to present a ripe, justiciable controversy, a declaratory judgment action "must be definite and concrete, touching the legal relations of parties having adverse legal interests," not merely "of a hypothetical or abstract character." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). Specifically, the Court has held that a declaratory-judgment dispute must have "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac.*

Coal & Oil Co., 312 U.S. 270, 273 (1941); *accord, e.g.*, *Lake Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 508 (1972).

Applying that standard, this Court has routinely held nonjusticiable declaratory-judgment actions that fail the requirements of ripeness and immediacy. For example, in *Texas v. United States*, 523 U.S. 296 (1998), the Court unanimously rejected as unripe a declaratory judgment action brought by a State to determine whether a potential future action authorized by a State statute under certain circumstances that were not yet present would trigger the preclearance provisions of the Voting Rights Act. *See id.* at 300 ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (internal quotation marks omitted)). And, in *Textron Lycoming Reciprocating Engine Division v. United Automobile, Aerospace & Agricultural Implement Workers of America*, 523 U.S. 653 (1998), the Court found no Article III controversy sufficiently ripe to support a union's declaratory-judgment action to determine the validity of a collective-bargaining agreement, because there was "no indication that [the employer] had any interest in defending the binding nature of the contract." *Id.* at 661. *See also Ashcroft v. Mattis*, 431 U.S. 171, 172-73 & n.2 (1977) (per curiam) (finding no "present, live controversy" supporting a declaratory judgment based upon "speculation" about potential future legal adversity); *Laird v. Tatum*, 408 U.S. 1, 10 (1972) (rejecting justiciability of declaratory judgment action based upon allegation "that the exercise of his First Amendment rights is being chilled by the mere existence, without more, of a governmental investigative and data-gathering activity").

The immediacy requirement has led to more specific ripeness tests in particular contexts. Of particular importance here, for example, the Court has made it clear that constitutional challenges to statutes fail to satisfy the case or controversy requirement unless there is an imminent threat of prosecution under the statue. Thus, in *Boyle v.*

Landry, 401 U.S. 77 (1971), the Court rejected constitutional challenges to particular State laws on particular facts because there was no "specific threat by any officer or official . . . to arrest or prosecute" the plaintiffs. *Id.* at 81. In the absence of any such concrete threat, any judicial resolution would involve improper "speculation about the future." *Id. See also Elec. Bond & Share Co. v. Secs. & Exch. Comm'n*, 303 U.S. 419, 443 (1938) (refusing to offer "an advisory decree upon a hypothetical state of facts" in a declaratory challenge to provisions of a regulatory statute not under threat of actual prosecution); 10B Charles Alan Wright, *et al.*, *Federal Practice and Procedure* § 2757, at 477-84 (3d ed. 1998) (noting that "courts have declined to hear cases seeking a declaratory judgment on the constitutionality of a particular statute or ordinance when plaintiff has not shown that there is any immediate threat that the statute will be enforced against him").

The Federal Circuit's "reasonable apprehension" test is a well-established analogue to the imminent threat of prosecution standard. It applies that standard, and more generally adapts the immediacy requirement, to the context of declaratory judgments over patent infringement and validity issues. Paralleling the requirement of an actual threat of prosecution in the statutory context, the "reasonable apprehension" test requires some threat or conduct by the patentee "which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." Pet. App. 27a. In short, the "reasonable apprehension" test flows naturally from this Court's cases, and plainly is not in conflict with them.

b. The petition claims that the decision below conflicts with several cases discussing the requirements for Article III standing. Pet. 9 (citing *Bennett v. Spear*, 520 U.S. 154 (1997), and *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83 (1998)). But both of these cases address only the requirements for standing, because it was the only justiciability requirement at issue in them. *See Bennett*, 520

U.S. at 160-61; *Steel Co.*, 523 U.S. at 88-89. Nothing in these cases purports to displace this Court's other cases holding that, in addition to standing, ripeness is also a prerequisite for justiciability. *See, e.g.*, *Allen v. Wright*, 468 U.S. 737, 750 (1984) (noting that justiciability involves "not only standing but mootness, ripeness, political question, and the like" (internal quotation marks omitted)); *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975) (discussing relationships among standing, ripeness, and mootness requirements). Indeed, *Steel Co.* noted that the standing requirements that it discussed comprised only "part of" the constitutional test for justiciability. 523 U.S. at 102.

Apotex asserts that *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), is somehow inconsistent with the decision below. But *Cardinal Chemical Co.* involved the unrelated issue whether an appellate determination of noninfringement renders moot a declaratory judgment counterclaim challenging the patent's validity. *See id.* at 89, 95. There was no question in that case that the declaratory judgment was ripe for adjudication in the first instance, because it followed an actual infringement lawsuit by the patent holder. *See id.* at 96 ("In this case, . . . it is perfectly clear that the District Court had jurisdiction to entertain Cardinal's counterclaim for a declaratory judgment of invalidity" because it "ha[d] actually been charged with infringement of the patent."). The dictum in that case regarding the scope of declaratory judgment jurisdiction in the first instance merely noted that "a party may satisfy" the case or controversy requirement "even if the patentee has not filed an infringement action," *id.* at 95, but nonetheless noted the "requirement for jurisdiction under the Act . . . that the conflict be real and immediate, *i.e.*, that there be a true and actual 'controversy,'" *id.* at 96 (internal quotation marks omitted). This is consistent with the "reasonable apprehension" test, which does not require an actual lawsuit, but merely some conduct creating a reasonable likelihood that one may be imminently brought.

Apotex's discussion of *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937), exhibits the same confusion on Apotex's part. Apotex suggests that *Aetna Life* conflicts with the "reasonable apprehension" standard because the declaratory judgment defendant in that case had not filed suit, yet jurisdiction was upheld. Pet. 10-11. Yet the "reasonable apprehension" test applied below does not require an actual lawsuit, but rather merely a reasonable apprehension of one being imminently filed. And the declaratory judgment defendant in *Aetna Life*, an insured, had taken concrete steps to put the plaintiff insurance company on reasonable notice of an adverse legal position, thus creating a reasonable apprehension of suit. *See* 300 U.S. at 237. Indeed, the insured had not only affirmatively "claimed the disability benefits" in question, but had "repeatedly renewed" those claims. *Id.* And, in finding a controversy that was ripe for resolution, the Court relied on those facts, finding that the dispute was not "hypothetical or abstract," but was ripe and immediate, *id.* at 240, because, "[p]rior to this suit, the parties had taken adverse positions with respect to their existing obligations," *id.* at 242. Indeed, *Aetna Life Insurance* is cited in this Court's cases for its recognition and application of the immediacy requirement. *See, e.g.*, *Md. Cas. Co.*, 312 U.S. at 273.

2. The decision below is also entirely consistent with the law in other circuits. In a footnote, the petition claims that there are "[c]onflicts between the Federal Circuit's decisions and those of other circuits." Pet. 13-14 n.6. In fact, both of the cases cited by Apotex expressly adopt the very same "reasonable apprehension" test as did the decision below, and thus merely reinforce the correctness and settled nature of that test.

United Christian Scientists v. Christian Science Board of Directors, 829 F.2d 1152 (D.C. Cir. 1987), *see* Pet. 14 n.6, involved a declaratory judgment action challenging the constitutionality of a law granting a copyright extension. 829 F.2d at 1154. The panel addressed the issue of subject-

matter jurisdiction in a footnote, and held that "[t]he 'actual controversy' requirement 'is satisfied when a defendant's conduct has created on the part of the declaratory plaintiff a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question,'" and where there has been infringing activity. *Id.* at 1158 n.25 (quoting *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985)) (internal quotation marks omitted). Like the decision below, the panel noted that, while "the declaratory defendant need not actually charge infringement" to satisfy this standard, the declaratory judgment plaintiff "must establish that his apprehension of infringement charges is reasonable and objectively manifested in light of the totality of the circumstances." *Id.* The panel found that the totality of the circumstances in the *United Christian Scientists* case constituted "an implied threat" of litigation sufficient to support jurisdiction over the declaratory judgment action. *Id.* In short, the D.C. Circuit expressly agreed with and applied the "reasonable apprehension" standard used in this case.

Similarly, *Sherwood Medical Industries, Inc. v. Deknatel, Inc.*, 512 F.2d 724 (8th Cir. 1975), held that jurisdiction over a declaratory judgment action must be supported by "conduct or [a] course of action on the part of the patentee which would lead a reasonable man to fear that he or his customers face an infringement suit or the threat of one if he continues or commences the activity in question." *Id.* at 728. The panel found that the declaratory judgment plaintiff in *Sherwood Medical* "ha[d] a 'reasonable apprehension' that it would be faced with an infringement suit if it commenced marketing its chest drainage device," in light of various circumstances, including a letter from the patent holder's attorney and statements made by "a high ranking employee" of the patent holder suggesting that it might sue. *Id.* Once again, the Eighth Circuit used the very same standard for subject-matter jurisdiction as did the decision below.

III. THE PETITION IS WRONG ON THE MERITS OF THE QUESTION PRESENTED.

Finally, the decision below is correct on the merits. The petition is wrong in arguing to the contrary; and the errors in its arguments further show why certiorari review is inappropriate in this case.

1. The district court correctly ruled that there is no present case or controversy between the parties that would support Apotex's declaratory-judgment action. In order for a constitutionally cognizable claim or controversy to exist, there must be an actual dispute between the parties that is both "immedia[te] and real[]." *Md. Cas. Co.*, 312 U.S. at 273. In this case, Apotex concedes the facts showing that there is no current dispute between the parties regarding the subject of its declaratory-judgment action, namely the validity or infringement of the '699 patent.

Significantly, no conceivable controversy over the '699 patent can occur for some time into the future, in light of Apotex's paragraph III certification with respect to the '518 patent — which Apotex acknowledges precludes it from obtaining approval for, or marketing, its generic product until after June 2006 without regard to the '699 patent — and Ivax's statutory exclusivity period following it. Apotex has not represented that Pfizer will choose to assert any patent claims against it based upon any generic product that Apotex may one day attempt to market. Indeed, Apotex concedes that Pfizer declined to bring any infringement action of its own in response to Apotex's ANDA filing, Pet. 4, and Apotex itself alleges that Pfizer will not commence such an infringement action, if any, until at least after Ivax's exclusivity period has run. These are precisely the circumstances constituting hypothetical future controversies that this Court has rejected as inadequate to support a justiciable declaratory-judgment action. *See, e.g.*, *id.*

As Judge Dyk indicated in his dissent from the Federal Circuit's denial of *en banc* review in the similar *Teva* case,

Pet. App. 65a, there is no case or controversy where the declaratory-judgment defendant has expressed no desire to enforce the right in question. *See Textron*, 523 U.S. at 661 (finding no case or controversy where there was "no indication that Textron had any interest in defending the binding nature of the contract" whose validity was the subject of the declaratory-judgment action). Here, as in *Teva*, Apotex itself claims that, far from having any desire to assert its patent rights against Apotex, Pfizer has an incentive "to *delay* infringement litigation," at least until some future time when the Ivax exclusivity period has ended. Pet. 16 (emphasis added). But, as Judge Dyk also recognized regarding the similarly situated generic manufacturer in *Teva*, Pet. App. 66a, it is not yet the case that Apotex "actually is about to manufacture or sell the drug"; and it is even more speculative whether, if Apotex did, Pfizer would at that point commence any infringement action. Therefore, under this Court's cases, there is no present controversy over the subject of Apotex's action.

2. No doubt in light of these facts, the petition does not primarily argue that there is any present dispute over the infringement or validity of the '699 patent. Instead, Apotex alleges that it "is injured," Pet. 11, by the (pre-Medicare Amendments) statutory scheme governing the ANDA process. Its alleged injury has nothing to do with a fear of suit by, or liability to, Pfizer, but rather rests on the claim that "the failure to secure a court judgment prohibits *the federal government* from approving" Apotex's product, Pet. i (emphasis added), and therefore that Apotex might be "prevent[ed from] marketing . . . a generic equivalent to Zoloft®," Pet. 4. Similarly, the Federal Circuit dissenters in the *Teva* case relied upon this same theory of an injury stemming from a delay in FDA approval under the Hatch-Waxman regime. Pet. App. 46a-47a (Mayer, J., dissenting), 56a-58a (Gajarsa, J., dissenting), 66a-68a (Dyk, J., dissenting). Indeed, the Federal Trade Commission, in a Federal Circuit *amicus* brief in *Teva*, acknowledged that the

panel's application of the "reasonable apprehension" standard would have been appropriate "in a classic patent declaratory judgment suit," FTC *Teva* Br., *available at* http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf, at 17 (last visited Apr. 6, 2006) (internal quotation marks omitted), but urged the Federal Circuit to create a special exception in the Hatch-Waxman context owing to this alleged injury from a delay in being able to obtain FDA approval, *see id.* at 18. These arguments are seriously confused and profoundly wrong.

A declaratory-judgment action allows the natural defendant in a dispute to initiate litigation over an injury that would have been the subject of the declaratory-judgment *defendant's* lawsuit that it has not yet initiated, but that is hanging over the head of the declaratory-judgment plaintiff. *See, e.g.*, *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 504 (1959) (holding that the Declaratory Judgment Act "allow[s] prospective defendants to sue to establish their nonliability"). The injury question in a declaratory-judgment action is whether there is a sufficient and immediate harm to the declaratory-judgment *defendant* to support its assertion of a cognizable claim against the declaratory-judgment plaintiff to allow the plaintiff to file an anticipatory action to declare its liability or nonliability for that injury. *See, e.g.*, *Md. Cas. Co.*, 312 U.S. at 273 ("It 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.").

For this reason, Apotex's reference to the injury that *it* allegedly suffers from a potential delay in starting Ivax's exclusivity period under the Hatch-Waxman procedures is ill-conceived. Pfizer is the declaratory-judgment defendant, and Apotex is the declaratory-judgment plaintiff. Thus, for purposes of determining whether a declaratory-judgment action about the '699 patent is justiciable, the question is whether *Pfizer* has suffered a legally cognizable injury that is ripe for adjudication, not whether Apotex has suffered a

legally cognizable injury that is ripe for adjudication. Any such injury to Apotex could perhaps conceivably supply standing for it to bring a direct, non-declaratory lawsuit involving proper parties premised on that injury; but it does not make ripe any declaratory-judgment controversy over the '699 patent, which Apotex itself alleges that Pfizer has no current interest in asserting against it. Apotex's alleged injury would not involve "the same" one as a direct patent-infringement claim brought by Pfizer, and thus cannot support declaratory-judgment jurisdiction for this case (as opposed to some other case involving the defendant who allegedly caused *that* injury). *Md. Cas. Co.*, 312 U.S. at 273.

This conceptual defect is presented particularly starkly in this case. Apotex's claimed injury is not only different from the fear of being called to account for Pfizer's claim of patent infringement, but it is the precise opposite of such a claim. Apotex's claimed injury results from its claim that Pfizer will *not* assert any patent rights against it for some time, if at all, and that Apotex will suffer a competitive disadvantage to Ivax as a consequence. Apotex thus in effect claims an injury from the very *lack* of any controversy over the '699 patent. Simply to expose the claim is to show why no declaratory-judgment action against Pfizer (as opposed to a lawsuit against Ivax or the FDA) is proper. Thus, this case is at the opposite extreme from a declaratory-judgment case like *MedImmune, Inc. v. Genentech, Inc.*, No. 05-608, 126 S. Ct. 1329 (Feb. 21, 2006), in which this Court has granted certiorari to consider the entirely distinct issue of whether a patent licensee must breach a license before commencing a declaratory-judgment action about it. As the Federal Circuit observed in that case, "[l]icensor and licensee always have adverse legal interests," 427 F.3d 958, 964 (Fed. Cir. 2005) (internal quotation marks omitted), and the declaratory-judgment plaintiff in that case relied upon the risk that the licensor would sue it if it stopped payment on the license. *See id.* at 963. The issues relating to genuinely adverse parties to a license are wholly unrelated to those in this case,

where the subject of the lawsuit is admittedly entirely different from the injury alleged to support it — and relates to a statutory scheme that has since been amended in key respects (and is not at issue in *MedImmune*).

It may be assumed, as Apotex alleges, that the 180-day exclusivity period for Ivax places Apotex at a competitive disadvantage. It may even be assumed, as Judge Dyk assumed (albeit perhaps incorrectly) in his *Teva* dissent, that, under the statute, Apotex cannot bring suit directly against either Ivax or the FDA to attempt to eliminate or shorten this competitive disadvantage. The constitutionally appropriate response to this competitive disadvantage is *not* to treat an unripe, hypothetical claim of infringement by Pfizer as nonetheless justiciable. Rather, as the *Teva* panel majority recognized, Pet. App. 40a, the constitutionally appropriate response to this situation is to deny justiciability and to allow Congress to amend the statute to address any perceived deficiencies in the legal regime that it created. And that, of course, is precisely what Congress did in the 2003 Medicare Amendments — which is just another reason why certiorari review of the decision below is plainly unwise and unnecessary.

3. Contrary to the claims of the petition, Pet. 14-19, the decision below is also entirely consistent with the intent of Congress in crafting the prospective provisions of the Medicare Amendments, and particularly the provision stating that declaratory-judgment actions may be brought outside the initial 45-day period for the patentee to sue. 35 U.S.C. § 271(e)(5). By its express language, that provision does not attempt to confer any new jurisdiction beyond that already available under the Declaratory Judgment Act, and contemplates that any such jurisdiction must be "consistent with the Constitution," *id.*, including the constitutional requirement that a real, immediate, and ripe case or controversy must exist.

Indeed, Congress left no doubt about whether it expected the "reasonable apprehension" test would survive the amendment. The Conference Committee Report repeatedly states that the drafters "d[id] not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction." H.R. Conf. Rep. No. 108-391, at 836 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 2187 (citation omitted). *See also id.* (stating expectation that courts would "apply the 'reasonable apprehension test'"); 149 Cong. Rec. S15,533-02, S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch) (noting that "the settled case law of the 'reasonable apprehension' test remains undisturbed"). The report also observes that "[i]n any given case, . . . a court may or may not find a reasonable apprehension of suit." H.R. Conf. Rep. No. 108-391, at 836, *reprinted in* 2004 U.S.C.C.A.N. at 2187.

The petition attempts to dismiss all of this legislative history in a conclusory footnote, Pet. 18 n.12, stating that it "obviously cannot be reconciled with the statutory text." Pet. 11 n.5. As shown above, the legislative history merely reinforces the plain meaning of the statutory text, and disproves Apotex's claims that the plain meaning is somehow contrary to the legislative intent.

Finally, a provision that would have purported to confer automatic jurisdiction such as Apotex urges here was proposed in the Senate, but was ultimately rejected. In the Senate bill, a patentee's failure to sue within 45 days of receipt of a paragraph IV notice would have "establish[ed] an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in . . . any action . . . for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed." Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong., § 702(c) (2003). The proposal was rejected in conference after Senator Hatch, co-sponsor of the

Hatch-Waxman legislation, expressed concern about the constitutionality of authorizing "subject matter jurisdiction for a declaratory judgment based on the failure to bring a suit . . . particularly in light of [the] manner in which the U.S. Courts of Appeals, including the Federal Circuit, have developed and applied the 'reasonable apprehension' test." 149 Cong. Rec. S8686, S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch).

In short, through the plain language of the Medicare Amendments, through the express articulation of the conference report, and through a rejection of a more expansive proposal, Congress endorsed the "reasonable apprehension" test and expected the courts to continue to apply it in cases under the amended statute. The petition has no proper basis for suggesting otherwise.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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