No. 05- 48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

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 did not intend to market the potentially infringing product in question for years, if ever, 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"), designated "Pfizer, Inc." in the caption, states that it has no parent and no publicly held company owns 10% or more of its stock.

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RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

In this action, Petitioner Teva Pharmaceuticals USA, Inc. ("Teva") seeks an advisory opinion on whether a generic pharmaceutical that it may someday attempt to market, but for which it concededly will not seek FDA approval until at least July 2006, infringes a patent that Teva itself alleges respondent Pfizer has no present interest in asserting against Teva. 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 its NDA filing, the NDA applicant must supply 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 Sept. 1, 2005).

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." *Id.* § 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 is 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.* § 505(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. Pet. App. 6a-7a & n.3.

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.

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 29, 2010, but Ivax's paragraph IV certification meant Ivax was seeking approval before that second patent expires.

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.

In July 2002, after Pfizer and Ivax had settled Pfizer's infringement lawsuit, Teva filed an ANDA seeking approval to market generic sertraline hydrochloride tablets. Like Ivax, Teva filed a paragraph III certification with respect to the '518 patent, thereby delaying any 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 Teva 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 Teva. Consequently, the '699 patent is not an obstacle to the FDA's approval of Teva's ANDA, which the FDA can approve immediately after the expiration of the period created by Teva'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 January 24, 2003, Teva sued Pfizer, seeking a declaratory judgment that Teva's proposed generic product would not infringe the '699 patent and that claims of the

'699 patent were invalid. Pfizer moved to dismiss the complaint for lack of subject matter jurisdiction and, on December 8, 2003, the district court granted Pfizer's motion.

The district court noted that there is jurisdiction under the Declaratory Judgment Act only where there is some "actual controversy" between the parties. Pet. App. 43a (internal quotation marks omitted). 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. 43a (internal quotation marks omitted).

Finding the first requirement satisfied, *id.*, the district court nonetheless found that there was no conduct by Pfizer creating any reasonable apprehension of an infringement suit. It noted that there need not be any "express charge of infringement" to satisfy this requirement, but found that there must be some conduct "indicat[ing] an intent on the part of the patentee to enforce its patent." Pet. App. 44a (internal quotation marks and brackets omitted). The district court concluded that neither Pfizer's mere listing of the '699 patent in the Orange Book, nor Pfizer's failure to commit *not* to sue Teva, nor Pfizer's previous record of enforcing patents against others, created any reasonable apprehension on the part of Teva that Pfizer would sue Teva to enforce the '699 patent. Pet. App. 44a-46a.

3. The Federal Circuit affirmed by a 2-1 vote. Judge Mayer dissented.

a. While noting that it was not the exclusive test of a "case" or "controversy," Pet. App. 20a, the 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. 13a. Evaluating "the totality of the circumstances," Pet. App. 15a (internal quotation marks omitted); *see also* Pet. App. 12a (considering "all the circumstances" of the case at hand (internal quotation marks omitted)), the panel majority found no case or controversy supporting Teva's declaratory-judgment action.

The panel majority concluded that "Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced," because this statutory obligation merely lists "patents with respect to which claims of infringement '*could* be reasonably asserted . . . .' 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however." Pet. App. 15a.

The panel majority also found insufficient "Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue." Pet. App. 15a. While finding these considerations to be "relevant to the analysis," *id.*, it determined that neither proved "dispositive in this case." Pet. App. 16a. The panel majority noted that "[a]ccording to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination," and thus was "unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent." Pet. App. 16a-17a.

The panel majority also rejected Teva's argument that the express provision for a declaratory judgment action after the 45-day period in the Medicare Amendments altered the outcome. The panel majority noted that the plain language of the revised section 271(e)(5) (Supp. 2004) stipulates that jurisdiction must be "consistent with the Constitution," thus acknowledging the governing case or controversy requirements. Pet. App. 18a, 21a. Because it found that the

parties' "adverse interests have not ripened into an actual controversy," Pet. App. 21a, the panel majority found that the statutory and constitutional standard for jurisdiction was not satisfied. The panel also reviewed the legislative history of the Medicare Amendments and determined that Congress had both rejected a proposal for declaratory judgment actions with more categorical language and embraced the "reasonable apprehension" standard in the conference report. Pet. App. 21a-24a. The panel concluded that "[i]f it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly." Pet. App. 26a.

b. In dissent, Judge Mayer did not reject the reasonable apprehension standard. Rather, he argued that "the filing of a[n NDA] and subsequent listing of a pharmaceutical patent in the [Orange Book] is conduct giving rise to a reasonable apprehension that an [ANDA] filer and declaratory judgment plaintiff will face a patent infringement suit." Pet. App. 27a.

c. By a 9-3 vote, the Federal Circuit denied Teva's petition for *en banc* review of the case. Pet. App. 49a. Judge Gajarsa wrote to express the view that the case should be analyzed under the three-part test for standing (requiring "concrete, actual or imminent injury in fact," causation, and redressability) announced in cases like *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998). Pet. App. 52a. Judge Dyk also wrote a dissent from the denial, though he agreed with the panel majority that there was no present controversy sufficient to satisfy Article III regarding Teva's infringement of the '699 patent, simply because Pfizer did not object to Teva's ANDA filing. Pet. App. 64a. Nor did Judge Dyk find any justiciable controversy over "whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement," because "Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from

doing so by the risk of infringement damages." *Id.* Nonetheless, Judge Dyk believed that there was a justiciable controversy "over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing," *id.*, even though he acknowledged that "[n]ormally, one would expect that the approval issue would be litigated between Teva and the FDA." Pet. App. 65a.

4. Teva filed the present petition for certiorari on July 5, 2005. Twenty days later, Teva and Ivax jointly announced "a definitive agreement providing for the acquisition of IVAX by TEVA," under which Ivax will become a Teva subsidiary. http://www.tevapharm.com/pr/2005/pr_536.asp (last accessed Sept. 1, 2005). Teva and Ivax announced that "[t]he transaction is expected to close in late 2005 or early 2006." The completion of that transaction would eliminate any incentive for Teva to pursue approval for the ANDA it filed, because Teva would have no interest in competing with its own subsidiary's generic product, or in shortening its own 180-day exclusivity period. Thus, the basis of Teva's claimed controversy, its alleged inability to cause Ivax's 180-day exclusivity period to start running through a court judgment of invalidity or non-infringement, will almost certainly never ripen into any actual dispute in light of its acquisition of Ivax.

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, even the concern expressed by Teva and the dissenting judges below has been abrogated by amendments to the operative ANDA regime. Further, the decision below is entirely consistent with this Court's decisions and the decisions of other courts; contrary to the petition, the decision below does not create any circuit split. 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. The correctness of the panel's decision is underscored by Teva's announced acquisition of Ivax, which not only confirms that there is no ripe dispute, but shows that it is unlikely there ever will be a mature dispute over the issue raised in the petition.

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 vehicle problems precluding review 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 Cemetary*, 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 asserts that there is a "financial incentive to *delay* the commencement of infringement litigation," Pet. 19, in order to avoid accelerating the 180-day exclusivity period awarded to the first generic applicant. The petition argues that, "[u]nless Teva can obtain a judicial determination whether its generic version of Zoloft[®] infringes Pfizer's patent, it cannot trigger IVAX's exclusivity and thereby avoid delaying the launch of its generic product until at least six months after the ['518] patent expires." Pet. 23. This was the issue that concerned the panel and en banc dissenters in the Federal Circuit. *See* Pet. App. 33a-34a (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. 55a (Gajarsa, J., dissenting) (claiming that Pfizer "insulated itself from any judicial determination" during the 180-day period); Pet. App. 65a (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 Teva's position (*i.e.*, a party who like Teva 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 and the dissents below 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. Contrary to the petition, the court below 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. 13a, indicated that it did not view that test as the only test of justiciability, Pet. App. 20a, and made clear that its application of that test was limited to the particular "totality of the circumstances" in the present case, Pet. App. 15a (internal quotation marks omitted); *accord* Pet. App. 12a.

Such a decision 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 second generic entrant must have no intent to market its product for several years.
- 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 court below held that, in the "totality of the circumstances," Pet. App. 15a (internal quotation marks omitted), no ripe case or controversy existed for adjudication. The Federal Circuit 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

panel acknowledged, for example, 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. 20a. And it found the facts relied upon by Teva to be "relevant" to the analysis, but not "dispositive" in the case at hand. Pet. App. 15a-16a. Noting that Teva had no intent to market its product for several years, Pet. App. 16a ("Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006."), and that Pfizer has shown no intent to enforce its patent rights before that time, Pet. 16a, the panel majority concluded that the parties' "adverse interests have not ripened into an actual controversy," Pet. App. 21a.

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. 20-25.

1. The Federal Circuit's reliance on and application of the "reasonable apprehension" standard is 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. MacMullen*, 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, Avco Corp. 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 State laws 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 application of 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. 13a. In short, the "reasonable apprehension" test flows naturally from this Court's cases, and plainly is not in conflict with them.

b. Teva claims that the *Aetna Life Insurance* case conflicts with the "reasonable apprehension" standard because "there is no hint in the Court's opinion that the insurer faced any threat of imminent litigation." Pet. 21-22. To the contrary, the declaratory judgment defendant in that case, an insured, had taken concrete steps to put the plaintiff insurance company on reasonable notice of an adverse legal position, and had created a reasonable apprehension of imminent 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 routinely 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.

The petition, like Judge Gajarsa below, Pet. App. 52a, also claims that the decision below conflicts with several cases discussing the requirements for Article III standing. Pet. 21-22 (citing *Bennett v. Spear*, 520 U.S. 154 (1997), and *ASARCO, Inc. v. Kadish*, 490 U.S. 605 (1989)). But these two 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; *ASARCO*, 490 U.S. at 613. 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).

2. The decision below is also entirely consistent with the law in other circuits. The petition relies primarily on *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), *Sankyo Corp. v. Nakamura Trading Corp.*, No. 04-1337, 2005 WL 602596 (6th Cir. Mar. 15, 2005) (unpublished), and *Societe de Conditionnement en Aluminium v. Hunter Engineering Co.*, 655 F.2d 938 (9th Cir. 1981), in support of its claim of a circuit split. Pet. 24-25; *see also* Pet. Ap.. 62a-63a (Dyk, J., dissenting). But these decisions are perfectly consistent with the decision below.

Contrary to the suggestion in the petition, *Sallen* did not "expressly reject[] the proposition that Article III requires a party seeking a declaration of his right to use the defendant's trademark in its internet domain name to demonstrate a reasonable likelihood that it will be sued for trademark infringement." Pet. 24. *Sallen* merely held that there was no need to apply the reasonable apprehension standard in a case where "the dispute had already progressed far *beyond* those cases in which a declaratory defendant only questionably threatened suit." 273 F.3d at 26 (emphasis added). In particular, in *Sallen*, the holder of a disputed internet domain name and the party holding a trademark allegedly infringed by it under a "cybersquatting" law had already litigated aspects of the dispute before a panel of the World Intellectual Property Organization. *See id.* That tribunal had ruled on the merits, and the panel had ordered the domain name transferred to the trademark holder. Under such circumstances, the First Circuit merely held that there was no need to speculate about potential future litigation, because the controversy was already "certain." *Id.* This holding in

no way conflicts with the application of the reasonable apprehension standard in situations where there has been no actual litigation; to the contrary, the First Circuit's discussion presupposes that this is the correct standard in such situations.

Sankyo Corp. is similarly consistent with the decision below. The panel in *Sankyo Corp.* found no justiciable case or controversy in a declaratory judgment action filed to determine the proper forum for as-yet unfiled legal claims available to the declaratory-judgment defendant. In doing so, if anything, the *Sankyo* panel authorized an even more stringent requirement for a case or controversy in the context of issues relating solely to the proper forum for resolving a dispute, because it found that the declaratory-judgment defendant "ha[d] threatened litigation against" the plaintiff, yet still found no case or controversy in light of the fact that the "declaratory judgment action [wa]s merely directed at resolving the forum for NTC's potential claims, which NTC may or may not pursue." 2005 WL 602596, at *4.

Societe de Conditionnement en Aluminium is likewise completely consistent with the decision below. *Societe de Conditionnement en Aluminium* relied upon an express threat of legal action by the declaratory-judgment defendant to support a finding that it was reasonable for the plaintiff "to feel apprehensive about possible patent infringement." 655 F.2d at 945. The Ninth Circuit adopted the "real and reasonable apprehension" standard used by the Federal Circuit below, *id.* at 944, expressly disclaimed any "need to decide exactly what evidence of a real and reasonable apprehension is required in all cases to meet the case or controversy standard," *id.*, and held that the actual manufacture of the allegedly infringing product coupled with an express threat of a lawsuit by the defendant satisfied that standard in the case at hand, *id.* at 945. The panel distinguished between the apprehension of suit and the apprehension of liability, indicating that the latter is required,

but did so not to indicate any weakened standard to support a case or controversy, but rather to clarify that a court need not engage in an inquiry to determine whether, as a matter of fact, an agent of the declaratory-judgment defendant who had threatened a lawsuit had the power to make litigation decisions for that entity. *See id.*

Finally, in a footnote, the petition erroneously relies on three additional cases in asserting a conflict among the federal courts on the question presented. Pet. 25 n.18 (citing *Starter Corp. v. Converse, Inc.*, 84 F.3d 592 (2d Cir. 1996) (per curiam), *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990), and *Dewey & Almy Chemical Co. v. American Anode, Inc.*, 137 F.2d 68 (3d Cir. 1943)). All three of these cases applied the same "reasonable apprehension" standard as that used by the Federal Circuit below, and found that standard satisfied in light of express threats of litigation by the declaratory-judgment defendants. Teva apparently cites these cases because they occasionally use a slightly different verbal formulation of the test, referring to an apprehension of "liability" rather than an apprehension of suit. *See Starter Corp.*, 84 F.3d at 595; *Hal Roach Studios, Inc.*, 896 F.2d at 1555; *cf. Dewey & Almy Chem. Co.*, 137 F.2d at 71. Yet the analysis in each case makes clear that this slight verbal variance has no analytical significance. Indeed, in *Hal Roach*, the panel on the very next page restates the standard as whether the plaintiff "had a 'real and reasonable apprehension' that it would be the subject of an infringement action if it continued with its use of the" products in question. 896 F.2d at 1556. There is simply no judicial conflict that would merit this Court's review.

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 suggesting to the contrary; and the errors

in its arguments further show why certiorari review is inappropriate in this case.

1. The Federal Circuit correctly ruled that there is no present case or controversy between the parties that would support Teva'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, Teva 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 substantial time into the future, in light of Teva's paragraph III certification with respect to the '518 patent — which Teva 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. Teva has not represented that it will ever attempt to market a generic ANDA product, let alone that Pfizer will choose to assert any patent claims against it based upon such a product. Indeed, Teva concedes that Pfizer declined to bring any infringement action of its own in response to Teva's ANDA filing; and Teva 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 below, Pet. App. 64a, there is no case or controversy where the declaratory-judgment defendant has expressed no desire to enforce the right in question. *See Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aero., & Agric. Implement Workers of Am.*, 523 U.S. 653, 661 (1998)

(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, Teva itself claims that, far from having any desire to assert its patent rights against Teva, Pfizer has a "financial incentive" *not* to assert those rights, at least until some future time when Teva may lawfully enter the market. Pet. 19. But, as Judge Dyk also recognized, Pet. App. 64a, it is complete speculation whether Teva will ever choose to market its product; and it is even more speculative whether, if Teva 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 Teva's action.

The hypothetical character of this lawsuit is underscored by the intervening facts, which show that it is unlikely ever to ripen into an actual dispute. As shown above, Teva and Ivax have now announced that Teva will acquire Ivax, and upon consummation of that transaction, Teva will have no incentive to pursue any application for a generic product to compete with that of its own Ivax subsidiary. This factual development, which also makes it unlikely that Teva will ever choose to proceed with this declaratory-judgment action in the future even if allowed to do so, proves that the Federal Circuit was correct in its prescient conclusion that the parties' "adverse interests have not ripened into an actual controversy." Pet. App. 21a.

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, Teva alleges that it has sustained an injury from 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 Teva "cannot trigger IVAX's exclusivity" without obtaining a declaration of non-infringement or invalidity,

and therefore that it might be "delay[ed in] in the launch of its generic product until at least six months after the ['518] patent expires." Pet. 23. Similarly, the dissenters below relied upon this same theory of an injury stemming from a delay in FDA approval under the Hatch-Waxman regime. Pet. App. 33a-34a (Mayer, J., dissenting), 55a (Gajarsa, J., dissenting), 65a (Dyk, J., dissenting). Indeed, the Federal Trade Commission, in an *amicus* brief below, acknowledged that the panel's application of the "reasonable apprehension" standard would have been appropriate "in a classic patent declaratory judgment suit," FTC Br. at 17 (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.* 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, Teva'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 Teva 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 Teva has suffered a legally cognizable injury that is ripe for adjudication. Any such injury to Teva 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 Teva itself alleges that Pfizer has no current interest in asserting against it. Teva'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. *Md. Cas. Co.*, 312 U.S. at 273.

This conceptual defect is presented particularly starkly in this case. Teva'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. Teva'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 Teva will suffer a competitive disadvantage to Ivax as a consequence. Teva 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.

It may be assumed, as Teva alleges, that the 180-day exclusivity period for Ivax places Teva at a competitive disadvantage. It may even be assumed, as Judge Dyk assumed (albeit perhaps incorrectly) in dissent, that, under the statute, Teva 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 panel majority recognized, Pet. App. 26a, 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. 14-20, 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). *See also id.* (stating expectation that courts would "apply the 'reasonable apprehension test'"); 149 Cong. Rec. 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.

The petition attempts to dismiss all of this legislative history in a conclusory footnote, Pet. 18 n.12, stating that it "does not reflect the intent of the conferees to apply the reasonable apprehension test" because one of the passages contains the phrase "to the extent required by the Constitution." The footnote ignores the other provisions of the legislative history lacking this qualification, which unquestionably endorse the "reasonable apprehension" standard. In any event, by again referring to the requirements of the Constitution, the legislative history to which the petition refers (like the statutory text) in effect embraces the traditional requirement of a real, immediate, and ripe controversy, including the "reasonable apprehension of suit" test.

Finally, a provision that would have purported to confer automatic jurisdiction such as Teva 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. 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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