Nos. 15-281 & 15-307

IN THE

Supreme Court of the United States

DAIICHI SANKYO, INC. and DAIICHI SANKYO CO., LTD.,
Petitioners,
v.
APOTEX, INC.,
Respondent.

MYLAN PHARMACEUTICALS, INC.,
Petitioner,
v.
APOTEX, INC.,
Respondent.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether an action seeking a declaration that the plaintiff's generic version of a drug, if marketed, would not infringe the defendant's patent, brought because the plaintiff cannot bring its drug to market during a period of exclusivity based on that patent absent a timely judgment of non-infringement, is nonjusticiable because the defendant has disclaimed any interest in enforcing the patent.

CORPORATE DISCLOSURE STATEMENT

Apotex Pharmaceuticals, Inc. is the parent company of Apotex Inc. No publicly held company owns 10% or more of its stock.

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STATEMENT

Respondent Apotex, Inc. filed suit against petitioners (in No. 15-281) Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd. (collectively "Daiichi"), seeking a declaratory judgment that Apotex will not infringe a patent for a drug used to treat hypertension, U.S. Patent No. 6,878,703 ("the '703 patent") owned, but disclaimed by Daiichi, in order to remove this patent as a barrier to approval of Apotex's generic version of the drug, enabling Apotex to get its product to market as soon as generic competition is permitted. Pet. App. 1a-2a.[1]

By virtue of the FDA's approval of its New Drug Application ("NDA") No. 21-286, Daiichi markets for the treatment of hypertension Benicar® tablets containing olmesartan medoxomil 5 mg, 20 mg, and 40 mg. Pet. App. 2a. Applicable law requires that NDAs seeking to market a new drug identify all patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G); 21 C.F.R. § 314.53(c). In its application, Daiichi listed two patents that it owns and that are listed as approved drug products in the FDA's list of "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." Pet. App. 2a. They are U.S. Patent Nos. 5,616,599 ("the '599 patent"), which covers olmesartan medoxomil, and the '703 patent, which covers methods of treating patients with olmesartan medoxomil; the application identified both as patents as to which a claim of patent infringement could reasonably be asserted. Pet. App. 2a. The '599 patent

[1] Unless otherwise noted, all citations are to the petition appendix in No. 15-281.

expires on October 25, 2016, and the '703 patent expires on November 19, 2021. Pet. App. 2a-3a.

In April 2006, petitioner (in No. 15-307) Mylan Pharmaceuticals, Inc. ("Mylan") filed an Abbreviated New Drug Application ("ANDA") seeking to market a generic version of olmesartan medoxomil, and stating (in what is referred to as a "paragraph IV certification") that the '599 and '703 patents were either invalid or would not be infringed by Mylan's proposed generic drug. Pet. App. 3a. On July 11, 2006, Daiichi disclaimed all claims of the '703 patent. Pet. App. 3a. It also requested that the FDA remove the '703 patent from the Orange Book. Pet. App. 4a. Daiichi then sued Mylan for infringement of the '599 patent, eventually prevailing in the ensuing litigation, and thereby preventing Mylan from marketing its drug until October 25, 2016. Pet. App. 3a-4a.

Although, the '703 patent was disclaimed by Daiichi, it remains listed in the Orange Book. Pet. App. 4a. Indeed, as the court of appeals observed, the D.C. Circuit has held that a patent owner's request to remove a patent from the Orange Book is not a sufficient basis to permit the FDA to do so. Pet. App. 4a (citing *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317-18 (D.C. Cir. 2010)).

Under applicable law, any manufacturer that wants to sell a generic version of a drug prior to the expiration of a patent must submit a paragraph IV certification to the FDA stating either that its drug product will not infringe a patent listed in the Orange book or that the patent is invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A). In June 2012, wishing to market its own generic version of olmesartan medoxomil, Apotex filed an ANDA containing a paragraph IV certification stating that

the '703 patent is invalid or will not be infringed by the manufacture, use, or sale of the Apotex's generic drug. Pet. App. 4a.

Apotex then brought an action against Daiichi seeking a declaratory judgment that its generic drug listed in its ANDA does not infringe the '703 patent. Pet. App. 1a-2a. Mylan moved to intervene as a defendant, alleging that it was the first generic filer for olmesartan medoxomil, and therefore is eligible for a 180-day period of first-generic-filer exclusivity after October 25, 2016, if it is able to launch its product more than 75 days before another generic filer obtains a judgment that that the '703 patent is either invalid or not infringed by its generic competitor. Pet. App. 5a.

The district court granted Daiichi's motion to dismiss for lack of subject matter jurisdiction because "both Daiichi and Apotex no longer hold any meaningful interest in the now disclaimed patent." Pet. App. 40a.[2] The court of appeals reversed, observing that unless Apotex can obtain a timely declaratory judgment that the '703 patent is invalid or will not be infringed by its generic drug, it will be injured by its inability to enter the market until Mylan's 180-day period of exclusivity following that expiration of that patent expires: "Until that period ends, Apotex cannot make sales, and delay of entry may have lingering effects on market share." Pet. App. 10a. Thus, the court added, "by any commonsense measure, the parties have substantial, concrete

[2] The district court denied Mylan's motion to intervene as moot, but that ruling was reversed by the court of appeals, which acknowledged Mylan's financial interest in enjoying a period of generic exclusivity, which it would lose if Apotex obtains a judgment that the that the '703 patent is invalid or not infringed. Pet. App. 7a-8a. That aspect of the decision below is not placed at issue by these petitions.

stakes in whether Apotex secures the non-infringement judgment it seeks to advance its entry into the market." Pet. App. 11a. The court therefore concluded that "Apotex has alleged facts supporting the conclusion 'that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Pet. App. 29a (quoting *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

ARGUMENT

Although dressed up in the peculiarities of the Hatch Waxman Act and its unique infringement scheme, at its heart this is a classic dispute between competitors. Apotex is trying to get its product to market, and Daiichi and Mylan are trying to delay it in order to avoid additional generic competition. Daiichi's patent remains listed in the FDA Orange Book, and that delays Apotex's ability to get its generic hypertension drug approved. That is a classic instance of a concrete, legally cognizable injury, fairly traceable to the defendant's challenged conduct (Daiichi's listing of its patent in the Orange Book), and fairly redressable by a favorable judgment (which will trigger forfeiture of the final 180 days of exclusivity that petitioners would otherwise enjoy and render Apotex's ANDA eligible for approval). A plaintiff asserting such an injury presents a justiciable case.

To be sure, petitioners are disinterested in defending the validity of the '703 patent, but unless Apotex can obtain the declaratory judgment it seeks, that patent will continue to inflict legally cognizable injury on Apotex, and there is no support for petitioners' novel claim that a defendant can obtain a dismissal of action seeking redress for tangible economic harm

merely because the defendant has no wish to mount a defense on the merits.

Nothing about this case warrants plenary review. The court of appeals engaged in a straightforward, if intensely fact-bound, application of the test for determining whether an action asserts a sufficient legal injury to render it justiciable. There is no disagreement in the lower courts about the questions presented, and the petitions present no issue of widespread importance. The fact that this case is so deeply intertwined with the reticulated statutory scheme that governs the approval of generic drugs makes it even more unsuitable for this Court's review.

There is also no reason to hold these petitions for the decision in *Spokeo v. Robins*, No. 13-1339, which turns solely on whether a statutory violation can confer standing in the absence of tangible injury. The barrier to market entry presented by the '703 patent presents a concrete economic harm utterly different from the action before the Court in *Spokeo*. Indeed, these petitions are likely filed for no reason other than delay; if petitioners can prolong this litigation beyond the statutory window for causing forfeiture of their market exclusivity period, they will succeed in their efforts to use the '703 patent to restrict generic competition. That is reason enough to deny these petitions.

I. THIS ACTION IS JUSTICIABLE.

Petitioners claim that the parties have no sufficient interest in this case to render it justiciable. Daiichi, for example, complains that the court of appeals "permitted respondent to use the declaratory-judgment process not to resolve a specific live grievance between the parties concerning patent infringement, but rather to obtain a judgment where a controversy has not

arisen (and never will arise)." Pet. 13 (No. 15-281) (citations, internal quotations, and ellipsis omitted). Mylan complains that because it was disclaimed, "the '703 patent cannot injure Apotex; it is a nullity." Pet. 20 (No. 15-307). These submissions ignore the consequences for Apotex because Daiichi listed the '703 patent in the Orange Book, where it remains.

As the court of appeals observed, whether a plaintiff has alleged a justiciable injury is governed by the test for whether a plaintiff has standing to sue under Article III of the Constitution: "Standing under Article III of the Constitution requires that an injury be concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." Pet. App. 9a (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)). This Court has repeatedly stated the test for a justiciable injury in similar terms. *See, e.g., Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014) ("To establish Article III standing, a plaintiff must show (1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision." (internal quotations, citations, and brackets omitted)); *Lexmark International, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1386 (2014) ("The plaintiff must have suffered or be imminently threatened with a concrete and particularized 'injury in fact' that is fairly traceable to the challenged action of the defendant and likely to be redressed by a favorable judicial decision."). This test is readily satisfied here.

First, Apotex will suffer a concrete, nonspeculative, and particularized injury in fact if it is not allowed to obtain a declaratory judgment of noninfringement. As the court of appeals explained, "[t]he stakes over which the parties are vigorously fighting are concrete and substantial: the amount of revenue there will be from sales of olmesartan medoximil, and who will get what portions of it, during a period of at least six months." Pet. App. 9a. All of this is properly alleged in Apotex's amended complaint. *See* Pet. App. 52a-55a (No. 15-307). Beyond that, as the court observed, "[o]nce Apotex enters [the market], Daiichi and Mylan can expect to lose sales they otherwise would have made. It is plausible, too, that entry by Apotex would produce prices noticeably lower than those Daiichi and Mylan would charge during a duopoly period (with Mylan the exclusive generic seller)." Pet. App. 11a.[3]

Petitioners quarrel with none of this. Daiichi even acknowledges that the "exclusivity period is a powerful incentive that can be worth hundreds of millions of dollars." Pet. 5 (No. 15-281). Yet, a plaintiff facing a barrier to market entry has identified a sufficient injury to support standing to sue; it has long been settled that a competitive injury flowing from barriers that delay entry into a market is a sufficient injury to confer standing to bring suit. *See, e.g., Geertson*,

[3] Notably, on this point the court of appeals quoted an FDA analysis concluding that, "[o]n average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price." Pet. App. 11a n.2 (quoting FDA, Center for Drug Evaluation and Research, *Generic Competition and Drug Prices* (last updated Mar. 1, 2010), www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

561 U.S. at 149-53 (holding that standing was properly predicated on a likely delay in the ability of a seed manufacturer to market its product).

To be sure, because Daiichi has disclaimed the '703 patent, there is no realistic possibility that it will sue Apotex for infringement of that patent. The threat of an infringement action, however, is not the injury that Apotex alleged, and not the injury that the court of appeals identified to support Apotex's standing. That injury is instead predicated on the continued listing of the '703 patent in the Orange Book, which acts as a barrier to the approval of Apotex's ANDA until the period of exclusivity expires. *Cf. Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278, 1297 (Fed. Cir. 2008) ("This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market.").

Second, the injury Apotex faces if its entry into the generic market is delayed because it cannot obtain a timely declaratory judgment is fairly traceable to the challenged conduct—Daiichi's submission of the '703 patent for listing in the Orange Book. When it submitted and identified that patent in its NDA, Daiichi took the position that it was valid and enforceable. To be sure, Daiichi subsequently disclaimed the '703 patent, acknowledging its unenforceability even as it laid the basis for its current justiciability challenge to potential competitors who might seek a declaratory judgment that would lead to the patent's removal from the Orange Book. Yet, despite its disclaimer, Daiichi's listing of the '703 patent continues to have adverse consequences for Apotex; it poses a barrier to Apotex's entry into the market. The FDA will not remove a

patent from the Orange Book even if it has been disclaimed and even if the holder of the patent requested its removal from the Orange Book; the D.C. Circuit has held that the FDA lacks statutory authority to permit a manufacturer to delist a patent on that basis. *See Teva Pharmaceuticals*, 595 F.3d at 1315-18. Again, petitioners quarrel with none of this; they do not doubt that the continued listing of the '703 patent operates as a barrier to Apotex's entry into the generic market prior to the expiration of the exclusivity period.

In this connection, it is worth considering petitioners' claim that once Daiichi disclaimed the patent, the patent becomes "a legal nullity," Pet. 15 (No. 15-281), or "something that never existed." Pet. 18 (No. 15-307) (internal quotations and citation omitted). In fact, the '703 patent continues to have significant legal and economic consequences for the parties. Because Daiichi listed the '703 patent in the Orange Book, where it remains, it continues to operate as a bar to the FDA's approve of Apotex's ANDA, as the court of appeals recognized. *See* Pet. App. 12a-14a. This point renders unavailing Daiichi's reliance on *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721 (2013). In that case, the Court held that Nike's covenant not to sue to enforce its trademark rendered Already's claim attacking the mark's validity moot because "Already's only legally cognizable injury—the fact that Nike took steps to enforce its trademark—is now gone and, given the breadth of the covenant, cannot reasonably be expected to recur." *Id.* at 732. In this case, however, Daiichi's listing of the '703 patent in the Orange Book continues to have adverse competitive consequences for Apotex.

Finally, the judgment that Apotex seeks will redress its injury. As the court of appeals explained after a detailed review of this complex statutory scheme, if Apotex can obtain a declaratory judgment not subject to appeal more than 75 days before Mylan begins to market its drug, that will trigger forfeiture of the exclusivity period that petitioners would otherwise enjoy. *See* Pet. App. 19a-29a. In this Court, moreover, petitioners voice no objection to the court of appeals' analysis of forfeiture under the applicable statutes. Thus, the declaratory judgment Apotex seeks would redress the injury at stake by removing the '703 patent as a barrier to Apotex's market entry.

For their part, petitioners equivocate about whether their submissions rest on standing or some other, unidentified justiciability doctrine, *see, e.g.*, Pet. 15 n.4 (No. 15-281) ("[T]he question presented in this case is best understood in terms of justiciability generally, rather than standing or mootness."); Pet. 16 (No. 15-307) ("The Article III defect here can be expressed not just as a lack of an actual case or controversy, but as a lack of standing on Apotex's part."). In any event, petitioners fail to identify any justiciability doctrine that precludes a plaintiff alleging an otherwise legally cognizable injury-in-fact, fairly traceable to the challenged conduct, and redressable by a favorable judgment, from bringing suit on the ground that its interests are somehow not sufficiently adverse to the party it has sued.

Rather than arguing that Apotex faces no tangible economic injury if its entry into the generic market is delayed, fairly traceable to Daiichi's listing of the '703 patent in the Orange Book, and that would be redressed by a favorable judgment, petitioners contend that this case is nonjusticiable because no one contends that the

'703 patent is currently valid and enforceable. *See* Pet. 12 (No. 15-281) (arguing that the parties "have no 'adverse legal interests' with respect to the patent-infringement question presented by this action"); Pet. 14 (No. 15-307) ("If this case proceeds to the merits, there will be no dispute on the merits."). Petitioners' novel claim that the parties must disagree on the merits for an action to be justiciable, however, is insupportable.

If the parties must disagree on the merits of an action for it to be justiciable, presumably a defendant could obtain dismissal of virtually any lawsuit as non-justiciable simply by announcing that it has no disagreement with the plaintiff on the merits. Indeed, on petitioners' view, one wonders how a federal court could ever enter a default or a consent judgment premised on a defendant's unwillingness to defend a case on the merits. Of course, the law does not so easily permit a defendant to defeat justiciability.

For example, in *INS v. Chadha*, 462 U.S. 919 (1983), the Court concluded that Chadha's challenge to his deportation, ordered after the House of Representatives vetoed the Attorney General's suspension of his deportation pursuant to a statute authorizing a one-house veto, *id*. at 923-28, was justiciable even though all the parties agreed that the one-house veto was unconstitutional, reasoning that the parties retained a tangible stake in the outcome of the litigation: "[T]he INS's agreement with Chadha's position does not alter the fact that the INS would have deported Chadha absent the Court of Appeals' judgment." *Id*. at 939. The Court acknowledged that there might be prudential reasons to refuse to hear the case if no defense of the one-house veto were presented, but those concerns were obviated because both Houses of Congress had

appeared and filed briefs defending the challenged statute. *See id*. at 940.

A similar claim was rejected in *United States v. Windsor*, 133 S.Ct. 2675 (2013). In that case, a taxpayer sued to obtain a refund of estate tax because the federal government refused to recognize the validity of her same-sex marriage by virtue of the Defense of Marriage Act. *See id*. at 2682-83. While the action was pending, the Attorney General announced that he would no longer defend the Act, but the "Bipartisan Legal Advisory Group" of the House of Representative ("BLAG") was then permitted to intervene in the district court to defend the Act, and both the United States and BLAG later appealed the district court's judgment in favor of the taxpayer to the court of appeals, and following affirmance, sought and obtained certiorari in this Court. *Id*. at 2683-84.

This Court rejected an argument that the action should have been dismissed because "once the President agreed with Windsor's legal position and the District Court issued its judgment the parties were no longer adverse." *Id*. at 2685. The Court explained that this view "elides the distinction between two principles: the jurisdictional requirements of Article III and the prudential limits on its exercise." *Id*. The Court observed that although "the Executive may welcome this order to pay the refund," that "does not eliminate the injury to the national Treasury if payment is made, or to the taxpayer if it is not." *Id*. at 2686. The Court acknowledged that when the parties are in agreement on the merits, there is a risk that "the Court faces a 'friendly, non-adversary, proceeding in which a party beaten in the legislature seeks to transfer to the courts an inquiry as to the constitutionality of a legislative act," *id*. at 2687 (citation, internal quotations, ellipses

and brackets omitted), but, in light of BLAG's vigorous defense on the merits, there was no prudential reason to decline to hear the case. *Id*. at 2687-89.

Petitioners' position similarly conflates the jurisdictional requirements for justiciability with prudential considerations. Because the '703 patent continues to delay Apotex's injury into the generic market, Apotex faces concrete injury, fairly traceable to Daiichi's listing of that patent in the Orange Book, and that is redressable by the judgment Apotex seeks. Given the economic interest that petitioners have in delaying a potential competitor's market entry, petitioners have a concrete stake in the outcome of this litigation as well. The fact that petitioners have no interest in defending the '703 patent on the merits raises only prudential considerations about the risk of non-adversarial litigation. Petitioners, however, make no prudential arguments. The questions presented in the petitions are limited to Article III's requirements for justiciability; petitioners have waived any arguments about prudence. *See* Pet I (No. 15-281); Pet. i (No. 15-307).

Petitioners' waiver is understandable. Any argument that there are prudential reasons to refrain from hearing this suit would be difficult to square with the congressional judgment reflected in the Hatch-Waxman Act, which entitles a generic drug manufacturer to challenge the listing of a patent in the Orange Book that might block its access to the market. *See* 35 U.S.C. § 271(e)(5); 21 U.S.C. § 355(j)(5)(C). Petitioners present no question about whether this action is unauthorized by the Hatch-Waxman Act, nor do they treat with the

court of appeals' detailed analysis of the statute.[4] Given the statutory authorization for Apotex's declaratory judgment action seeking access to an important market, there is no basis to claim that prudential considerations overcome a statutory directive; as this Court has explained, a court "cannot limit a cause of action that Congress has created merely because 'prudence' dictates." *Lexmark*, 134 S. Ct. at 1388.

In any event, this case presents no realistic threat of collusive, friendly, or otherwise non-adversarial litigation; the parties are fierce competitors vying for position in an intensively competitive market. Daiichi's unwillingness to defend the '703 patent is a strong indication of its legal inefficacy, not a hint of collusion. For this reason, this case presents even weaker prudential arguments against justiciability than *Chadha* or *Windsor*. In those cases, the Executive truly welcomed a judgment invalidating the challenged statutes. Here,

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[4] Although petitioners do not take issue with the Federal Circuit's analysis of the pertinent statutory provisions, Mylan briefly claims that Senator Kennedy once expressed doubt about whether an action challenging a patent could be brought once its owner indicated that it would not seek to enforce it. *See* Pet. 27 (No. 15-307). In fact, during the congressional consideration of the declaratory-judgment provisions that govern this case, Senator Kennedy expressed the view that listing a patent in the Orange Book inflicts sufficient injury to give rise to a justiciable case or controversy:

> We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 CONG. REC. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).

given their economic interests, we can have confidence that petitioners have no desire to aid Apotex in its efforts to compete against them.

Indeed, if petitioners had no real stake in the outcome of this litigation, it is difficult to explain why they have engaged highly competent counsel, doubtless paying handsome attorney's fees, to defend an action of no economic significance to their businesses. Petitioners' shareholders should wonder at such a strategy. The explanation for this seeming anomaly, of course, is that petitioners have potent incentives to use whatever litigating strategy is most likely to inhibit competition from Apotex. Likely understanding that any effort to enforce the '703 patent was doomed, Daiichi instead disclaimed it, subsequently resisting Apotex's market entry through a justiciability defense, but this provides no hint of collusion.

There is, in short, neither a constitutional nor a prudential reason to refuse to hear a case simply because Apotex's competitors have concluded that any defense on the merits would be hopeless.

II. THIS CASE DOES NOT MERIT PLENARY REVIEW.

This case presents no question that warrants plenary review. Petitioners, for example, refrain from claiming that the decision below is irreconcilable with the law in any other circuit. Daiichi tries to minimize this obstacle to plenary review by writing that "the absence of a circuit conflict on the specific question presented is unremarkable, because the Federal Circuit has exclusive jurisdiction over appeals relating to patents." Pet. 20 (No. 15-281). If petitioners were correct, however, that there is ample authority supporting their claim that a defendant's unwillingness to

defend its challenged conduct on the merits renders a case nonjusticiable even if that conduct continues to have tangible economic consequences for the parties, one would expect that petitioners could identify some authority to support such a claim somewhere in the lower courts. In fact, petitioners identify no case in which a defendant's prior conduct has continuing consequences remotely comparable to the barrier to entry that Daiichi's listing of the '703 patent presents for Apotex, and in which justiciability was defeated merely because the defendant disclaims any interest in mounting a defense on the merits.[5]

Nor do the interests of justice demand plenary review to avoid the supposed threat that the decision below will open the courthouse doors to litigants asserting only ideological or abstract injuries. Given that the court of appeals' holding rests on the specific features of the Hatch-Waxman Act and its amendments, it is doubtful that the holding has any application outside this unique context. Moreover, the holding below is limited to cases in which the plaintiff establishes that

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[5] In the decisions in the lower courts that petitioners claim stand in tension with the decision below, the claimed injury had no tangible economic significance to the parties but rather involved entirely speculative harm. *See, e.g., Shell Gulf of Mexico, Inc. v. Center for Biological Diversity, Inc.*, 771 F.3d 632, 636-37 (9th Cir. 2014) (oil company could not sue environmental group based on agency's approval of its oil response plan because it feared group might sue agency and challenge the plan); *Collin County v. Homeowners Ass'n for Values Essential to Neighborhoods*, 915 F.2d 167, 170-72 (5th Cir. 1990) (county could not sue homeowner's group that it feared might challenge agency's approval of the county's environmental impact statement); *3V, Inc. v. CIBA Specialty Chemicals Corp.*, 587 F. Supp. 2d 641, 645-46 (D. Del. 2008) (action challenging Board of Patent Appeals' decision recognizing preclusive effects of a patent was mooted by its subsequent disclaimer).

a defendant's challenged conduct continues to have concrete adverse economic consequences for the plaintiff. *See* Pet. App. 10a-11a. Entertaining a lawsuit in that context, absent any bona fide concern about collusive or otherwise non-adversarial litigation, would surely advance the interests of justice by preventing Daiichi's disclaimer from effectively insulating a duopoly from competition. *Cf. Chadha*, 462 U.S. at 939 ("[I]t would be a curious result if, in the administration of justice, a person could be denied access to the courts because the Attorney General of the United States agreed with the legal arguments asserted by the individual."). Surely the interests of the public in fostering fair competition in this important market argue against plenary review here.

Plenary review is particularly inappropriate because this case may well become moot before it can be decided. Mylan is eligible to enter the market on October 25, 2016. Unless Apotex can obtain a declaratory judgment not subject to a right of appeal more than 75 days before Mylan enters the market, Apotex will not be able to enter the market prior to the end of the 180-day period of generic exclusivity in which competition in this market would be limited to petitioners' drugs. This will enable Daiichi and Mylan to enjoy an effective six-month duopoly. Thus, on the realistic assumption that Mylan will market its generic drug as soon as it can, if Apotex cannot obtain a timely "final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken" that the '703 patent is invalid or not infringed, likely by the summer of 2016, this case will become moot. *See* 21 U.S.C. § 355(j)(5)(D)(i)(bb)(AA). It is entirely unclear that these petitions, if allowed to proceed to the merits, can be briefed, argued, and decided in time to prevent mootness. Petitioners, for

their part, will have little incentive to brief the case promptly; delay alone wins this litigation for them. This is all the more reason to deny plenary review.

III. THIS CASE SHOULD NOT BE HELD.

Mylan asks that its petition be held pending disposition of *Spokeo, Inc. v. Robins*, No. 13-1339. *See* Pet. 14-15, 28-30 (No. 15-307). Daiichi, more tentatively, raises that possibility as well. *See* Pet. 19 n.5 (No. 15-281).

The question presented in *Spokeo* is:

> Whether Congress may confer Article III standing on a plaintiff who suffers no concrete harm, and who therefore could not otherwise invoke the jurisdiction of a federal court, by authorizing a private right of action based on a bare violation of a federal statute.

Pet. i (No. 13-1339). In that case, Robins brought suit against Spokeo alleging violations of the Fair Credit Reporting Act ("FCRA"), based on inaccurate information about him found in a website maintained by Spokeo, though the court of appeals acknowledged that "Robins's allegations of injury were sparse." *Robins v. Spokeo, Inc.*, 742 F.3d 409, 410 (9th Cir. 2015), *cert. granted*, 135 S. Ct. 1892 (2015) (No. 13-1339). "For example, the website allegedly described Robins as holding a graduate degree and as wealthy, both of which are alleged to be untrue. Robins, who is unemployed, described the misinformation as 'caus[ing] actual harm to [his] employment prospects.'" *Id*. at 411 (brackets in original), The court of appeals nevertheless concluded that Robins' allegations were sufficient to confer on him standing to sue because the FCRA did not require proof of actual injury: "When, as here, the statutory cause of action

does not require proof of actual damages, a plaintiff can suffer a violation of the statutory right without suffering actual damages." *Id*. at 413.

In *Spokeo*, the Ninth Circuit interpreted the FCRA to confer standing even if a plaintiff can identify no tangible harm flowing from a false statement in a credit report. Indeed, it is far from clear that Robins alleged any tangible harm; Spokeo's alleged misstatements seemed to enhance rather than harm his creditworthiness. Spokeo's petition accordingly presents only the question whether a statute can confer standing even in the absence of any "concrete harm." Pet. i (No. 13-1339). Unsurprisingly, in its opening brief, Spokeo repeatedly stresses that its submission is that standing is lacking absent some "concrete harm." *E.g.*, Pet. Br. 2, 3, 8, 9, 10 (No. 13-1339). It also acknowledges that "a variety of types of harm . . . can constitute injury in fact, including pecuniary loss [and] lost business opportunities." *Id*. at 7; *see also id*. at 37. Thus, if this Court reverses in *Spokeo* and holds that the Constitution requires a FCRA plaintiff to allege some tangible economic harm flowing from misstatements about him, such a holding would have no bearing on this case.

As we explain above, the decision below is predicated on concrete harm—the barrier to market entry posed by Daiichi's listing of the '703 patent in the Orange Book. Nor does the statute governing this case permit litigation absent a concrete harm—it permits a plaintiff to seek a declaratory judgment only when the plaintiff seeks to market a product that might infringe a patent listed in the Orange Book. *See* 21 U.S.C. § 355(j)(5)(C)(i). The statute therefore requires a plaintiff to allege that it seeks to pursue a business opportunity that would otherwise be lost by virtue of

the listed patent. Apotex's complaint alleges just this form of injury. *See* Pet. App. 52a-55a (No. 15-307). Accordingly, even if this Court embraces the petitioner's submission in *Spokeo*, nothing in that submission casts the slightest doubt on the sufficiency of the competitive injury asserted by Apotex here.

Although there is no plausible account that would justify holding these petitions for a decision in *Spokeo*, a hold would have enormous consequences for this litigation, effectively handing petitioners an undeserved victory. As we explain above, if Apotex cannot resolve this litigation by the summer of 2016, it is likely that this case will become moot. Thus, a hold would effectively resolve this litigation in favor of petitioners, stifling competition in the relevant market until the period of exclusivity expires. A hold, accordingly, would work a manifest injustice in this case.

CONCLUSION

The petitions for certiorari should be denied.

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