No. 15-281

In the Supreme Court of the United States

DAIICHI SANKYO, INC., AND DAIICHI SANKYO CO., LTD., PETITIONERS

v.

APOTEX, INC.

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

REPLY BRIEF FOR THE PETITIONERS

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In its brief in opposition, respondent does not dispute three fundamental propositions. *First*, Article III of the Constitution limits federal jurisdiction to disputes between parties with adverse legal interests. *Second*, petitioners disclaimed the '703 patent and thus are legally disabled from enforcing it. *Third*, in the underlying action, respondent is seeking a declaratory judgment that its generic drug product would not infringe the '703 patent—a patent that, as a result of the disclaimer, is treated as if it never existed.

Given its failure to dispute those propositions, respondent cannot seriously argue that the Federal Circuit's decision was correct. Particularly in light of this Court's recent decision in *Already, LLC* v. *Nike, Inc.*, 133 S. Ct. 721 (2013), it is clear that a justiciable controversy concerning patent infringement does not exist where the patentee cannot enforce the patent, even where a plaintiff seeking a declaratory judgment of noninfringement contends that the judgment may redound to its benefit for other reasons. And respondent does not seriously challenge the importance of the Federal Circuit's decision, which allows access to federal court based solely on economic injury. If that decision is permitted to stand, it will destabilize a familiar and important limitation on the jurisdiction of the federal courts. This Court should grant review and reverse the Federal Circuit's deeply flawed decision.

A. The Court of Appeals' Decision Conflicts With This Court's Decisions Concerning The Limits On Article III Jurisdiction

The Federal Circuit's decision conflicts with this Court's decisions confining federal jurisdiction to disputes that are "definite and concrete, touching the legal relations of parties having adverse legal interests." *North Carolina* v. *Rice*, 404 U.S. 244, 246 (1971) (per curiam) (citation omitted). As noted above, respondent does not dispute that fundamental principle, nor does it dispute that it is seeking a declaratory judgment concerning a controversy—*viz.*, whether its generic drug product would infringe the '703 patent—that has not arisen (and, because of the disclaimer of that patent, will never arise). As a result, respondent has effectively admitted that it brought this action as a "medium for securing an advisory opinion." *Coffman* v. *Breeze Corps.*, 323 U.S. 316, 324 (1945). To the extent respondent attempts

to reconcile the Federal Circuit's decision with this Court's decisions concerning the case-or-controversy requirement, that attempt is unavailing.

1. As explained in the petition, the Federal Circuit's decision conflicts with this Court's recent decision in *Already*—a decision that respondent all but ignores. Compare Pet. 13-17 with Br. in Opp. 9. There, the Court held that Already's counterclaim for trademark invalidity did not present a justiciable case or controversy because Nike had issued a covenant not to enforce its trademark against Already. See 133 S. Ct. at 732. So too here, respondent concedes that "there is no realistic possibility that [petitioners] will sue [respondent] for infringement of [the '703] patent." Br. in Opp. 8. That is for the simple reason that petitioners have disclaimed the patent and thus can no longer enforce it. See Pet. 6-7.

Respondent attempts to distinguish *Already* by contending that it is suffering "adverse competitive consequences" as a result of the continued listing of the '703 patent in the Orange Book. Br. in Opp. 9. But the Court in *Already* specifically rejected the "boundless theory" that "a market participant is injured for Article III purposes whenever a competitor benefits from something allegedly unlawful," such as the "mere existence" of an invalid trademark. 133 S. Ct. at 730-731. Under the reasoning of *Already*, respondent's only "legally cognizable injury * * * is now gone," and the mere fact that FDA "may base decisions" concerning market entry on a nonexistent patent "does not give rise to the sort of 'concrete' and 'actual' injury necessary to establish" a justiciable case or controversy between petitioners and respondent. *Id.* at 730, 732 (citation omitted).

2. Throughout its brief, respondent repeatedly asserts that its injury is predicated not on the threat of enforcement of the '703 patent against it, but rather on

FDA's "continued listing of the '703 patent in the Orange Book" (which gives rise to the 180-day exclusivity period that prevents respondent from entering the generic market sooner). Br. in Opp. 8; see, *e.g.*, *id.* at 4, 6, 9, 10, 13, 16, 19. That asserted injury, however, is entirely incongruent with the relief respondent is seeking in this action—namely, a declaratory judgment of non-infringement against petitioners. See *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007) (noting that a declaratory-judgment action must concern a dispute that is "real and substantial and admit[s] of specific relief through a decree of a conclusive character" (internal quotation marks and citation omitted)).

Citing *Monsanto Co.* v. *Geertson Seed Farms*, 561 U.S. 139 (2010), respondent contends that "it has long been settled that a competitive injury flowing from barriers that delay entry into a market is sufficient injury to confer standing to bring suit." Br. in Opp. 7. In *Monsanto*, the Court held that a company had standing to appeal an order that prevented it from marketing its product until a government agency completed a required environmental impact statement. See 561 U.S. at 149-150.

This case critically differs from *Monsanto* because respondent's asserted "injury in fact" does not "result[] from the action which [it] seek[s] to have the court adjudicate." *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 473 (1982). To the extent respondent asserts an injury arising from the continued listing of the '703 patent, the Orange Book is maintained by FDA, not petitioners. As respondent concedes (Br. in Opp. 2), particularly in light of Mylan's paragraph IV certification, the continued listing of the '703 patent in the Orange Book is beyond petitioners' control: petitioners have requested

that FDA delist the '703 patent, but FDA has refused to do so. See Pet. 6 & 14 n.3. And respondent does not contend, nor could it, that FDA would delist the '703 patent simply because respondent obtains a declaratory judgment of non-infringement.

Respondent cites a Federal Circuit decision, *Caraco Pharmaceutical Laboratories, Ltd.* v. *Forest Laboratories, Inc.*, 527 F.3d 1278 (2008), to support the proposition that FDA's continued listing of the '703 patent renders this action justiciable. See Br. in Opp. 8. In *Caraco*, the Federal Circuit held that a generic drug manufacturer could seek a declaratory judgment of non-infringement against a brand-name manufacturer even where the brand-name manufacturer had issued a covenant not to sue on its patent. See 527 F.3d at 1297. The court asserted that a justiciable controversy existed because the listing of the patent in the Orange Book "effectively prevent[ed] the FDA from approving [the generic manufacturer's] ANDA and thus exclud[ed] [it] from the drug market." *Ibid.*

Respondent's reliance on *Caraco* is misplaced. As a preliminary matter, *Caraco* was decided before *Already*, where this Court held that a covenant not to sue eliminated a party's only legally cognizable injury. See p. 3, *supra*. And even if respondent were correct that the decision in this case is consistent with *Caraco*, that does not alter the fact that the decision conflicts with this Court's precedent. To the extent that *Caraco* also holds that legal adversity is unnecessary to give rise to an Article III case or controversy, it merely demonstrates just how far the Federal Circuit has strayed from this Court's Article III jurisprudence—and just how essential it is for this Court to reject the Federal Circuit's expansive approach.

3. Respondent repeatedly asserts that petitioners are "unwilling[] to defend the '703 patent." Br. in Opp.

14; see, *e.g.*, *id.* at 4, 5, 11, 13, 15, 16. Based on that assertion, respondent contends that petitioners are making a "novel claim" that, for purposes of Article III jurisdiction, "the parties must disagree on the merits for an action to be justiciable." *Id.* at 11. But that is a blatant mischaracterization of petitioners' position. It is not that petitioners are *unwilling* to defend the '703 patent, but rather that there is nothing left to defend: as a result of petitioners' disclaimer, petitioners are legally *unable* to assert any rights under the patent (and lack any control over the exclusivity resulting from FDA's continued listing of the patent).

For that reason, *INS* v. *Chadha*, 462 U.S. 919 (1983), and *United States* v. *Windsor*, 133 S. Ct. 2675 (2013), are inapposite. In *Chadha*, although the Executive Branch agreed with the respondent's position on the merits, that agreement "d[id] not alter the fact that the [Executive Branch] would have deported [the respondent] absent the Court of Appeals' judgment." 462 U.S. at 939. Similarly, in *Windsor*, although the Executive Branch chose "not to defend the constitutionality" of the challenged legislation, it continued to enforce the legislation by denying the respondent a tax refund. 133 S. Ct. at 2685-2687. "It would be a different case," the Court noted, "if the Executive had taken the further step of paying [the respondent] the refund to which she was entitled under the District Court's ruling." *Id.* at 2686. In both cases, the alleged injury was "fairly traceable to the challenged action of the [Executive Branch], and not the result of the independent action of some third party not before the court." *Id.* at 2685 (alterations and citation omitted).

Here, by contrast, respondent has no cognizable claim to relief against petitioners, for the simple reason that the '703 patent has been disclaimed. This action is thus more akin to one in which a plaintiff challenges a

repealed or expired statute than to one in which the Executive Branch declines to defend the constitutionality of an existing statute. And as to the former situation, the Court has held that a declaratory-judgment action regarding a repealed or expired statute is, "of course, inappropriate." *Diffenderfer* v. *Central Baptist Church of Miami, Florida, Inc.*, 404 U.S. 412, 414-415 (1972) (per curiam); see *Burke* v. *Barnes*, 479 U.S. 361, 363-364 (1987).

4. In a last-ditch effort to support Article III jurisdiction, respondent asserts that the Hatch-Waxman Act "entitles a generic drug manufacturer to challenge the listing of a patent in the Orange Book that might block its access to the market." Br. in Opp. 13. But that is misleading. The Hatch-Waxman Act provides only that a generic drug manufacturer may bring an action against a brand-name manufacturer seeking a declaration that a listed patent is invalid or would not be infringed. See 21 U.S.C. 355(j)(5)(C); 35 U.S.C. 271(e)(5). Indeed, the statute makes clear that the plaintiff in a Hatch-Waxman Act declaratory-judgment action may bring suit only "to the extent consistent with the Constitution." 35 U.S.C. 271(e)(5). And insofar as respondent is arguing that provisions of the Hatch-Waxman Act give rise to Article III jurisdiction, it merely underscores the propriety of holding this petition pending the Court's decision in *Spokeo, Inc.* v. *Robins*, No. 13-1339 (to be argued Nov. 2, 2015). See Pet. 19 n.5.

B. The Question Presented Is An Exceptionally Important One That Warrants The Court's Review

If allowed to stand, the Federal Circuit's decision will work mischief in the federal judiciary by permitting lawsuits to proceed in the absence of legal adversity between the parties. Respondent's arguments as to why

the Court should nevertheless deny review are unpersuasive.

1. Respondent argues that the absence of a circuit split on the specific question presented—*viz.*, whether a declaratory-judgment action concerning a disclaimed patent may constitutionally be heard in an Article III court—weighs against granting the petition. See Br. in Opp. 15-16. But respondent does not dispute that no conflict could ever arise on that specific question, because the Federal Circuit has exclusive jurisdiction over appeals relating to patents. See Pet. 20.

Instead, respondent merely disputes the broader proposition that the Federal Circuit's approach is inconsistent with that of other circuits, which have held in other contexts that non-legal interests are insufficient to give rise to an Article III case or controversy. See Br. in Opp. 15-16. But both *Shell Gulf of Mexico, Inc.* v. *Center for Biological Diversity, Inc.*, 771 F.3d 632 (9th Cir. 2014), and *Collin County* v. *Homeowners Association for Values Essential to Neighborhoods*, 915 F.2d 167 (5th Cir. 1990), held that legal adversity is required, while the decision below holds that it is not. See Pet. 18-19.

Rather than coming to grips with the reasoning of *Shell* and *Collin County*, respondent dismisses them in a footnote as involving "entirely speculative harm" that had "no tangible economic significance to the parties." Br. in Opp. 16 n.5. But the harm in those cases was no more speculative or intangible than it is here. In *Shell*, an oil company sought to forestall "substantial economic effects" it feared would result from litigation by environmental groups aimed at overturning environmental response plans approved by a federal agency. 771 F.3d at 636-637. The court held that, in the absence of "adverse legal interests," such economic effects did not cre-

ate Article III jurisdiction; the only legal adversity was between the environmental groups and the agency. *Ibid.*

Similarly, in *Collin County*, a county sued to preclude litigation by a homeowner's group intending to challenge the construction of a highway that had been cleared by a federal agency. 915 F.2d at 169-170. The county asserted that it would "benefit greatly from the improved access" provided by the road and had "expended considerable resources" to prepare it. *Id.* at 170. But the court held that the county's "interests in the outcome of potential litigation" were not "adverse legal interests" for Article III purposes. *Ibid.* If the homeowner's group had intended to initiate litigation, the court explained, the "proper defendant would have been" the federal agency, not the county. *Id.* at 171.

So too here, respondent has sued petitioners, with which it has no legal adversity, for an alleged injury it admits is based solely on FDA's continued listing of the '703 patent. See Br. in Opp. 8. Any legal adversity that exists regarding that listing is between respondent and FDA. See, *e.g.*, *Teva Pharmaceuticals USA, Inc.* v. *Sebelius*, 595 F.3d 1303, 1311-1315 (D.C. Cir. 2010) (holding that a first-filing generic drug manufacturer has Article III standing to sue FDA regarding patent listing). The Federal Circuit's reasoning here, on analogous facts, therefore cannot be reconciled with the reasoning of the Fifth and Ninth Circuits—or with the reasoning of this Court in its decisions concerning the limits on Article III jurisdiction.

2. Respondent's argument that the case "may well become moot before it can be decided" also misses the mark. Br. in Opp. 17-18. As a preliminary matter, respondent does not dispute that it has not yet received tentative approval from FDA—without which it cannot trigger forfeiture of Mylan's exclusivity. See Pet. 7. Nor

does respondent provide any indication that such approval is forthcoming or will be granted before Mylan is able to begin marketing its generic drug product on October 25, 2016.

In any event, even if respondent did have tentative approval, there would be more than sufficient time for the Court to decide this matter. Should the Court grant review in this case, it would presumably hear argument and issue a decision in the October 2015 Term, potentially enabling respondent to trigger forfeiture before Mylan is able to enter the market (in the event, of course, that respondent also obtains tentative approval from FDA).

3. Finally, respondent argues that the Federal Circuit's decision should remain undisturbed because of "the interests of the public in fostering fair competition in this important market." Br. in Opp. 17. But the Hatch-Waxman Act's exclusivity period is a "pro-consumer device" because it "induce[s] challenges to patents claimed to support brand drugs." *Teva*, 595 F.3d at 1318. By deputizing federal courts to aid the efforts of later-filing generic manufacturers that bring suit solely to defeat the exclusivity rights of first filers, the decision below undermines the procompetitive incentives created by the exclusivity period. See Pet. 20-21.

In any event, whether the Federal Circuit's decision has procompetitive or anticompetitive effects is largely beside the point. The central question presented here is whether Article III of the Constitution permits access to federal court based solely on economic injury and in the absence of legal adversity. This Court has already rejected the "boundless theory" that "a market participant is injured for Article III purposes whenever a competitor benefits from something allegedly unlawful." *Already*, 133 S. Ct. at 731. The Federal Circuit offered no valid

justification for adopting a different rule in the context of declaratory-judgment actions concerning disclaimed patents. This Court should grant certiorari and reverse the Federal Circuit's outlying decision.*

* * * * *

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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* After petitioners filed their petition, Mylan filed a petition of its own from the Federal Circuit's judgment. See *Mylan Pharmaceuticals Inc.* v. *Apotex, Inc.*, No. 15-307 (filed Sept. 8, 2015). That petition presents materially identical questions, and makes materially identical arguments, to those presented here. As respondent notes, Mylan was not permitted to intervene in the district court, and it was therefore neither a party to the judgment entered by the district court nor an appellee before the court of appeals. See Br. in Opp. 3 n.2. As a generic manufacturer, however, Mylan may offer a distinctive perspective on the issues presented here. For that reason, the Court may wish to grant Mylan's petition in addition to this one, notwithstanding Mylan's status in the lower courts. At a minimum, the Court should grant this petition and hold Mylan's petition.