No. 08-624

In the Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S, PETITIONERS

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD., RESPONDENT

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

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The Hatch-Waxman Act provides that any generic drug manufacturer that has filed an abbreviated new drug application with the FDA, and wishes to establish that its product does not infringe any Orange Book-listed patent of the name-brand drug, may bring a declaratory judgment action for that purpose. The Act vests the federal courts with subject matter jurisdiction over such actions "to the extent consistent with the Constitution." 31 U.S.C. § 271(e)(5).

Within that framework, the question presented is:

Whether a name-brand drug manufacturer's unilateral "covenant not to sue" for infringement of an Orange Book-listed patent deprives the federal courts of Article III jurisdiction to hear a generic drug manufacturer's challenge to that patent, where (1) the covenant not to sue does not concede that the generic product does not infringe the patent, and (2) the generic drug manufacturer is barred from entering the market and selling its product absent a judicial ruling on non-infringement.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondent Caraco Pharmaceutical Laboratories, Ltd. states that it is a subsidiary of Sun Pharmaceutical Industries Ltd., which is the only publicly held company owning 10% or more of Caraco's stock.

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BRIEF FOR RESPONDENT IN OPPOSITION

This case involves the question whether federal courts possess jurisdiction under the Hatch-Waxman Act to resolve a generic drug manufacturer's challenge to Orange Book-listed patents, where the patentee agrees not to sue for infringement but refuses to concede that the generic product does not infringe. Applying settled principles of Article III jurisprudence, the court of appeals issued a carefully reasoned opinion concluding that respondent Caraco suffered an injury in fact (exclusion from the market for generic Lexapro®) that is traceable to petitioners' conduct (listing their patents in the Orange Book) and redressable by a finding of non-infringement—which would accelerate Caraco's market entry, potentially by several years.

The result below is compelled by this Court's recent decision in *MedImmune, Inc.* v. *Genetech, Inc.*, 549 U.S. 118, 128 (2007), which held that a paid-up patent licensee was injured by having to pay royalties on a patent—and thus could challenge its validity in federal court—even though the licensee was subject to "no risk" of infringement liability. As the court of appeals recognized, Caraco's injury is much greater: it is not merely forced to pay royalties on the sales of its product; it is forbidden from selling that product *at all*, for as long as there is an unresolved dispute over the underlying patents. But even if the court below had misapplied *MedImmune* (and it did not), certiorari would not be warranted to address the application of a recent precedent of this Court to a particular case arising on an interlocutory basis in the unique context of the pre-2003 Hatch-Waxman Act. Indeed, not *one* Federal Circuit judge voted to grant rehearing.

Aware that the court below broke no new ground in terms of standing law, petitioners attempt to portray its decision as having created a new cause of action—one unauthorized by the statute. As explained below, however, the decision below faithfully implements the Hatch-Waxman Act—which entitles *any* generic manufacturer that files an abbreviated new drug application to a judicial decision on whether its product infringes the patents at issue, and which provides that a ruling in favor of *any* such generic manufacturer can trigger the first filer's 180-day exclusivity period. Review should therefore be denied.

STATEMENT

A. The Hatch-Waxman statutory scheme

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act"), 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271, which governs the approval of new and generic drugs. The Act is designed to "[strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." Pet. App. 3a.

1. Abbreviated new drug applications

To streamline the approval of generic drugs, the Act allows drug manufacturers to submit to the Food and Drug Administration ("FDA") an abbreviated new drug application ("ANDA"), instead of a full new drug application ("NDA"). 21 U.S.C. § 355(j)(2)(A). The ANDA process allows generic manufacturers to rely on safety and efficacy studies previously submitted by name-brand companies in NDAs. The timing and approval of an ANDA, however, depends largely

on the patent protections covering the name-brand drug. Pet. App. 4a; *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

When a name-brand drug company files an NDA, it must identify all non-process patents that protect the new drug. 21 U.S.C. § 355(b)(1), (c)(2). Exercising a "ministerial duty" (Pet. 6), the FDA lists these patents in its book of "Approved Products With Therapeutic Equivalence Evaluations"—the "Orange Book." In filing its ANDA, a generic manufacturer must include one of four certifications for each patent listed in the Orange Book: (I) a statement that the required information relating to the patent has not been filed with the FDA; (II) a statement that the patent has expired; (III) a statement that the patent will expire on a particular date; or (IV) a statement that the patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These certifications are known as Paragraph I, II, III, and IV certifications, respectively.

When, as in this case, an ANDA contains a Paragraph IV certification challenging an Orange Book-listed patent, the Act treats the filing of the ANDA as an act of patent infringement (35 U.S.C. § 271(e)(2)), and the patentee may sue the ANDA applicant for infringement. If the patentee does not sue within 45 days, the FDA may approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues, however, the ANDA is automatically stayed for 30 months or until a court holds each listed patent not infringed (or invalid), whichever comes first. *Ibid.* "[T]he purpose of subsection[] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme rests." *Eli Lilly*, 496 U.S. at 678.

To "incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible," the pre-2003 version of the Act, at issue here, provides 180 days of market exclusivity for the generic applicant that is the first to challenge each Orange Book-listed patent. Pet. App. 6a. This "first applicant" or "first filer" receives a 180-day monopoly on the right to market its generic drug, which is triggered on either the date that it begins such marketing (the "commercial-marketing trigger") or the date of any final court decision finding the challenged patent invalid or not infringed (the "court-judgment trigger")—whichever comes first. Pet. App. 6a-7a; see generally *Teva Pharm. USA, Inc.*, v. *Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005).

Subsequent ANDA filers may not receive FDA approval until the first applicant's 180-day exclusivity period has expired. 21 U.S.C. § 355(j)(5)(B)(iv). This creates a potential "bottleneck": if the first applicant cannot (or does not) use its exclusivity, the patentee can leverage the unexpired exclusivity to keep other generics out of the market, sometimes for decades. For example, if the first applicant unsuccessfully challenges one of the listed patents for which it was the first Paragraph IV filer, other generic applicants remain barred from entering the market—unless they can obtain a court decision holding the other patents not infringed or invalid. *Ibid.* Patentees thus have a tremendous incentive "to insulate [their] patent[s] from any validity challenge" and "from any judicial determination of the[ir] metes and bounds." *Teva Pharm. USA, Inc.* v. *Pfizer Inc.*, 405 F.3d 990, 993 (Fed. Cir. 2005) (Dyk, J., dissenting from denial of rehearing en banc).

Patentees attempt to insulate their drug patents from challenge in several ways: (1) by opportunistically suing on only one Orange Book-listed patent while holding the others in reserve for future litigation, *e.g.*, *Teva Pharm. U.S.A., Inc.* v. *Novartis Pharm.*, 482 F.3d 1330, 1343 (Fed. Cir. 2007); (2) by settling on advantageous, duopolistic terms with the first ANDA applicant and refusing to litigate with later applicants, *e.g.*, *Teva*, 405 F.3d at 993 (Dyk, J., dissenting from rehearing en banc); and—as here—(3) by suing subsequent ANDA applicants on one listed patent while covenanting not to sue on the others. Each of these actions injures subsequent ANDA applicants, frustrates "early resolution of patent disputes," *Novartis*, 482 F.3d at 1344, and undermines "Congress's intent to foster early generic market entry," *Teva*, 405 F.3d at 995 (Dyk, J., dissenting from denial of rehearing en banc).

2. The "civil action to obtain patent certainty"

"[T]o prevent patentees from 'gaming' the Hatch-Waxman Act," Congress enacted the "civil action to obtain patent certainty" (or "CAPC"). *Novartis*, 482 F.3d at 1342. The CAPC allows any ANDA applicant to bring a declaratory judgment suit challenging any Orange Book-listed patent. 21 U.S.C. § 355(j)(5)(C). As Congress recognized:

> [When] the brand drug company [attempts] . . . to delay a final court decision that could trigger [the first filer's exclusivity] . . . generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book . . . because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (Sen. Kennedy).

Such a "declaratory action is the ideal method to police [patentees'] strategic manipulation of the Hatch-Waxman exclusivity provisions" (*Teva*, 405 F.3d at 995 (Dyk, J., dissenting from denial of rehearing en banc)) and to "facilitate[] the early resolution of patent disputes between generic and pioneering drug companies." Pet. App. 5a. The Act thus extends federal jurisdiction over these ANDA declaratory judgment actions to the full extent permitted by the Constitution. 35 U.S.C. § 271(e)(5).

B. Caraco's ANDA

Forest holds an FDA-approved NDA for Lexapro®, which comprises the active ingredient escitalopram oxalate. Lexapro®, a profitable anti-depressant, generates more than $2 billion in annual sales—over half of Forest's gross revenue. Forest currently faces no generic competition on Lexapro®. *Forest Labs., Inc.* v. *Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

Forest's NDA for Lexapro® listed two patents in the Orange Book: U.S. Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The '712 patent, which expires in 2012, is directed to "substantially pure" forms of escitalopram; the '941 patent, which expires in 2023, is directed to particles of escitalopram oxalate with an average size of forty microns. *Ibid.*[1]

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[1] After the decision below, Forest listed a third patent—U.S. Patent No. Re. 7,420,069. Pet. 12 n.6. On November 26, 2008, Caraco filed a Paragraph IV certification challenging this patent, which like the '941 patent expires in 2023. This patent does not change the jurisdictional analysis. For simplicity, therefore, we refer only to the '712 and '941 patents.

Caraco wishes to market a generic version of Lexapro® based on particles of less than three microns. Caraco's ANDA, filed in 2006, challenged both of Forest's Orange Book-listed patents.

C. Ivax's exclusivity

Ivax Pharmaceuticals, not Caraco, was the first generic to file Paragraph IV certifications challenging Forest's '712 and '941 patents. To block approval of Ivax's ANDA, Forest sued Ivax on the '712 patent (but not the '941 patent). The Federal Circuit held that the '712 patent was valid, and that Ivax's proposed generic drug infringed it. *Forest*, 501 F.3d at 1272. At that point, Ivax lost its exclusivity on the '712 patent.

Having failed to obtain a favorable ruling on the '712 patent, Ivax is barred from entering the market for generic Lexapro® until the '712 patent expires in 2012 or another applicant defeats that patent. And because Ivax has a right to 180 days of market exclusivity on the '941 patent (as first filer on that patent under the pre-2003 provisions at issue here), no other generic manufacturer can enter the market until 180 days after Ivax—*i.e.*, until at least 180 days after the '712 patent expires in 2012—even if that manufacturer has a non-infringing product.

The Act allows subsequent generic ANDA filers to clear this "bottleneck" in one of two ways. In the immediate term—*i.e.*, before the '712 patent expires in 2012—they must successfully challenge both listed patents. In the slightly longer term—*i.e.*, after the '712 patent expires in 2012—they need only successfully challenge the second patent. After (1) both patents are ruled invalid or not infringed, or (2) the first patent has expired and the second has been ruled in-

valid or not infringed—either of which would trigger Ivax's 180-day exclusivity period—Caraco (and possibly other generics) can enter the market for generic Lexapro®.

Forest therefore has a strong incentive "to do everything possible to prevent its patents from being put in play." *Teva*, 405 F.3d at 994 (Dyk, J., dissenting from denial of rehearing en banc). As long as Forest can prevent the courts from ruling on its patents, it can bar all generic competition on Lexapro®, possibly until 2023, but certainly until 2012.

D. The district court's decision

As with Ivax, Forest sued Caraco on the '712 patent—but not the '941—to block approval of Caraco's ANDA while insulating the '941 patent from challenge. Desiring to clear the "bottleneck," Caraco filed a CAPC against Forest, seeking "a declaration that one or more claims of the '941 patent will not be infringed by [Caraco's product]." Pet. App. 99a.

Forest moved to dismiss the suit, initially arguing that there was no jurisdiction because Caraco lacked a "reasonable apprehension" that it would be sued for infringement. Following *MedImmune*, however, the Federal Circuit abandoned the "reasonable apprehension of suit" test in *Novartis*, 482 F.3d at 1338-1339. As the court there recognized, the fact that Caraco "is not legally free to enter the market . . . [is] a direct legal injury [caused by] the actions that [Forest] ha[d] already taken—[Forest's] listing of [its] patents in the Orange Book and [Forest's] suit against [Caraco] challenging the validity of [Caraco's] ANDA." *Id.* at 1345. The dispute over the '941 patent thus involves "a present injury sufficient for a justiciable controversy." *Ibid.*

Fifteen days after *Novartis*, and in a desperate attempt to avoid a ruling on Caraco's claim, Forest granted Caraco a unilateral "covenant not to sue" on the '941 patent and asserted that this "mooted" the controversy. Pet. App. 19a. Yet Forest refused to concede that the '941 patent was not infringed. Instead, Forest argued that the court should dismiss the case because eliminating the threat of infringement liability relieved Caraco of its only injury. *Id.* at 21a.

After twice changing its mind during argument, the district court dismissed the case without written opinion. The court did not explain why the continuing controversy over infringement of the '941 patent (which Forest refused to concede) or the delayed entry to market due to that controversy was insufficient to support standing. It simply applied the discredited "reasonable apprehension of suit" test, stating: "There's a covenant not to sue on the '941 so there's . . . no threat of a lawsuit . . . and no controversy." Pet. App. 77a-78a. The court of appeals found "no indication in the record that the district court considered either the Supreme Court's *MedImmune* decision or [the Federal Circuit's] *Novartis* decision when making this ruling." *Id.* at 20a.

E. The court of appeals' decision

The Federal Circuit reversed. Observing that the "reasonable-apprehension-of-suit test was overruled by *MedImmune*," the court explained that jurisdiction no longer turned solely on the risk of an infringement suit. Pet. App. 22a. Rather, the court was "guided by the Supreme Court's three part framework for determining whether an action presents a justiciable Article III controversy," under which "proving a reason-

able apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test." *Id.* at 22a, 23a.

The court went on to explain that "Caraco's alleged injury-in-fact"—"being excluded from selling a non-infringing product"—is "precisely the type of injury that the Declaratory Judgment Act is designed to remedy." Pet. App. 24a, 29a. "[A] potential competitor in other fields is legally free to market its product in the face of an adversely held patent," the court explained, whereas "an ANDA filer . . . is not legally free to enter the market [without FDA approval]." *Id.* at 24a. But "[i]f Caraco is correct that its generic drug does not infringe Forest's [patents], then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions . . . is exactly the type of injury-in-fact that is sufficient to establish Article III standing." *Id.* at 25a.

Turning to the traceability prong of standing, the court held that "[i]t is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather Forest's actions." Pet. App. 26a. Specifically, in "list[ing] its [Lexapro®] patents in the FDA's Orange Book," Forest "create[d] an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete"—"even if [Caraco's product] does not infringe" the Lexapro® patents. *Id.* at 26a-27a. Citing several precedents of this Court, the court found it "well settled that the creation of such barriers to compete satisfies the causation requirement of Article III standing." *Id.* at 27a.

As to redressability, the court reasoned that "a declaratory judgment . . . would clear the path to FDA approval that Forest's actions would otherwise deny Caraco"—and thus "eliminate the potential for the '941 patent to exclude Caraco from the drug market." Pet. App. 27a-28a. "In claiming that it has been denied the right to sell non-infringing drugs," Caraco alleged "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action . . . was enacted to prevent." *Id.* at 25a, 29a.

The court further held that the case was ripe. Delaying Caraco's suit would "ha[ve] the 'immediate and substantial impact' of forestalling Caraco's ability to activate Ivax's exclusivity period through the court-judgment trigger"—delaying Caraco's market entry "until at least 181 days after the '712 patent expires in 2012," if not "indefinitely," and generating "lost profits." Pet. App. 26a, 32a-34a.

As to mootness, the court acknowledged that "[i]f a threat of suit was the *only* action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case." Pet. App. 34a (emphasis added). But "[a] controversy *also* exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA," and "the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed." *Id.* at 37a (emphasis added). Thus, "Forest's covenant not to sue does not eliminate the controversy." *Ibid.*

Judge Friedman dissented. In his view, the possibility that a first ANDA filer "might not market its product upon either the expiration of the thirty month stay period or of the patents" is too "uncertain"

to support a declaratory judgment action. Pet. App. 39a. He did not dispute, however, that being kept out of the market injures Caraco, that Caraco's injury is traceable to Forest, or that *even if* Ivax went to market in 2012, a judgment invalidating the '712 and '941 patents *prior to* that date would enable Caraco to enter the market earlier (potentially by years) than it otherwise could. Nor did the dissent take issue with the legal standards applied by the majority. *Id.* at 40a. He simply believed that Caraco's only injury depended on whether Ivax delayed entering the market in 2012, and that this injury was not ripe.[2]

REASONS FOR DENYING THE PETITION

Petitioners concede that "the CAPC action should be interpreted as broadly as possible consistent with the bounds of Article III." Pet. 22. Not surprisingly, they do not suggest that Caraco's exclusion from the market is an insufficient injury to support standing. Nor do they dispute that Forest's listing of its patents in the Orange Book is one significant "but for" cause of Caraco's delayed market entry, or that a ruling in Caraco's favor would redress that injury. In short, there is no dispute over the basic principles of Article III jurisdiction that govern this dispute—or even, for the most part, over how they apply.

Rather, the petition rests on two statutory arguments. First, noting that "an injury must be action-

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[2] Judge Friedman also believed that, even under the pre-2003 Act, a first ANDA filer can "lose its right to exclusivity" if it "unreasonably delays" marketing its product. But as the court of appeals recognized (Pet. App. 32a), since Ivax filed its ANDA before Congress passed the "failure to market provision" (21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)), that provision does not govern Ivax's exclusivity.

able" to support standing, petitioners say the court below "recast the familiar cause of action for patent infringement as a cause of action that Congress has never seen fit to create." Pet. 15, 17. Second, they say that Caraco's injury is not attributable to Forest because Forest was "compelled" to list its patents in the Orange Book, and because any 180-day delay is caused by Ivax's "first filer" status. Both of these arguments, however, mischaracterize the Hatch-Waxman Act and the extent of Caraco's injury.

As explained below, the Act grants not only the first ANDA filer, but *any* ANDA filer, the right to a decision on whether its product infringes any listed patents; moreover, a ruling in favor of *any* such ANDA filer can trigger the first filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Thus, there is no basis to petitioners' suggestion that the court below recognized a cause of action not authorized by Congress.

Moreover, listing its patents in the Orange Book was "mandatory" only insofar as Forest wished to receive the benefit of a monopoly protected by the Act's stringent patent enforcement system—a benefit that depends on the validity and lawful scope of those patents. And quite apart from any delay attributable to Ivax's 180-day exclusivity period, Forest's listing of its patents *independently* causes Caraco to experience market delay—potentially several years' worth of delay—that more than suffices to support standing.

Beneath petitioners' mischaracterizations of the Act, all that remains is their quarrel with the court of appeals' carefully-reasoned application of settled jurisdictional principles to a particular Hatch-Waxman dispute. But the decision below is compelled by this

Court's decision just two Terms ago in *MedImmune*, which held that declaratory relief remains available even *absent* risk of infringement liability, provided there remains a substantial controversy between the parties—which exists here on account of Forest's refusal to concede non-infringement. And even if the court below had misapplied *MedImmune*, there would be no need for the Court to take up the general principles that govern standing in patent cases for the second time in as many years—particularly in this case, which is a relic of the pre-2003 statutory regime. Certiorari should therefore be denied.

I. The Petition Provides No Basis For Reviewing The "Legally Protected Interest" Holding Of The Decision Below.

Forest acknowledges (as it must) Congress's power to define what constitutes a "legally protected interest." Pet. 17. As this Court has observed, "Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy." *Massachusetts* v. *EPA*, 549 U.S. 497, 516 (2007). Moreover, Forest does not dispute that being kept out of the market is a cognizable Article III injury. Nor could it. Numerous decisions of this Court, recognized by the court of appeals (Pet. App. 27a), confirm that "a barrier that makes it more difficult" to "compete on an equal footing" can support standing. *E.g.*, *Northeastern Fla. Chapter, Assoc. Gen. Contractors of Am.* v. *Jacksonville*, 508 U.S. 656, 666 (1993).

Unable to quarrel with the general principles that govern whether Caraco has suffered an injury, Forest attempts to justify review by maintaining that Hatch-Waxman offers no protection for Caraco's interest in

entering the market with a non-infringing product. According to Forest, the Federal Circuit "recast the familiar cause of action for patent infringement" as one "premised on a nonexistent right to seek review of any action by a pioneer drug company that contributed to preventing a generic company from marketing its drug." Pet. 15, 20.

Even if this were so, it would raise only a question of statutory interpretation, not standing, and Forest has not sought review of the Federal Circuit's reading of the Act. See Pet. i (raising only jurisdictional issues). Any complaint that the court below misread the Act is not presented by the petition and cannot support certiorari. As shown below, however, the petition badly mischaracterizes both the Act and the reach of the decision below. Certiorari is therefore unwarranted for that reason as well.

A. Forest's assertion that the decision below rewrote the "civil action to obtain patent certainty" mischaracterizes the Hatch-Waxman Act.

To read the petition, one would think the Hatch-Waxman Act granted only *first* ANDA filers the right to challenge name-brand drug companies' patents. Yet Forest fails to provide any reason to question the Federal Circuit's conclusion that *any* generic's inability to market its product due to a name-brand company's patent listings is an injury that the CAPC is designed to address.

Indeed, with one exception discussed below (the Federal Circuit's recent *Janssen* decision, which Forest misinterprets), Forest cites not a single authority to support its assertion that subsequent ANDA applicants have no cognizable interest in obtaining rulings

that their products do not infringe—and thus in getting their ANDAs approved. See Pet. 20-25. Instead, Forest simply *assumes* that avoiding liability for infringement is Caraco's only "legally protected interest," and proceeds from that assumption to lambaste the jurisdictional analysis of the court below. But Forest's assumption is wrong—and once that becomes clear, nothing remains of its suggestion that the court below departed from "bedrock" principles of Article III standing.

When a generic drug maker's ANDA contains a Paragraph IV certification challenging the infringement (or validity) of an Orange Book-listed patent, the Act treats the very filing of the ANDA as an act of patent infringement. 35 U.S.C. § 271(e)(2). NDA filers such as Forest are well served by this provision—which this Court has recognized as necessary "to enable the judicial adjudication upon which the ANDA . . . scheme rests." *Eli Lilly*, 496 U.S. at 678.

But to "level the playing field" (*Novartis*, 482 F.3d at 1342), the CAPC also permits *any* ANDA filer—whether the first or any other—to obtain a decision on whether each patent at issue is invalid or not infringed. Similarly, any ANDA filer can set in motion the 180-day exclusivity period, and speed its FDA approval, by obtaining a favorable decision on the merits. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); 21 U.S.C. § 355(j)(5)(C); see also *id.* § 355(j)(5)(D)(i)(I)(bb)(AA) (providing that a successful CAPC by "any other applicant" can trigger forfeiture of the first filer's exclusivity). The Act thus grants *each* ANDA applicant a statutory right to a ruling on whether its generic product infringes valid Orange Book-listed patents.

What is more, Congress extended jurisdiction over such declaratory judgment actions to the full extent permitted by the Constitution. 31 U.S.C. § 271(e)(5). Without analysis or citation of authority, Forest declares that "the Federal Circuit erred in converting that interpretive instruction into an authorization to create a freestanding cause of action for any injury experienced by ANDA filers traceable in any respect to the blocking patent holder." Pet. 22. But the Federal Circuit has done no such thing. It has merely held—in decisions of three different panels—that the CAPC reaches disputes over infringement that block an ANDA filer's ability to reach market with a non-infringing product. See Pet. App. 25a, 29a; *Novartis*, 482 F.3d at 1345; *Janssen Pharmaceutica, N.V.* v. *Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008).

Indeed, even if the question "is whether the civil action to obtain patent certainty . . . creates a private right of action apart from redressing disputes over infringement" (Pet. 19), there *is* a dispute over infringement here. Forest carefully crafted its unilateral "covenant not to sue" to avoid conceding non-infringement. True, Caraco faces no risk of *liability* for infringement. But as the court below recognized (Pet. App. 25a), potential liability is not the only type of harm that declaratory judgment suits are designed to prevent (let alone the only type of harm that Article III recognizes). Suits seeking a declaration that one's product does not infringe a competitor's patents also prevent harm in the form of delayed market entry, and such an injury undisputedly satisfies Article III. Indeed, all that Forest has done is promise not to sue Caraco for damages that Caraco cannot inflict: If Caraco may not pursue its claim, then it cannot bring its product to market regardless of the covenant; and

if Caraco prevails, its product is non-infringing and Forest could not sue it regardless of the covenant.[3]

In sum, even if the court below had misread the scope of the CAPC, that mistake would be a matter of statutory interpretation on which Forest has not sought review; it would not amount to a conflict in the law of standing, let alone a "judicial legerdemain" regarding any "bedrock constitutional requirement." Pet. 15. But in any event, the court properly interpreted the scope of the CAPC. Accordingly, review should be denied.

B. Petitioners' policy-based concerns are unfounded.

Once it becomes clear that Forest's objection to the decision below is foreclosed by the Act itself, nothing remains of the parade of policy horribles offered to support certiorari.

1. For example, Forest and its amici assert that the decision below upsets the Act's "careful balance" between innovation and competition. Pet. 31-35; Ivax Br. 3-5; Pfizer Br. 19-21; WLF Br. 21-22. But since Congress provided that *any* ANDA filer could bring a declaratory judgment action to challenge the listed patents (and, if successful, trigger the 180-day exclusivity period), the ruling at issue in fact implements that balance.

Indeed, an ANDA filer's CAPC is especially appropriate where, as here, the first filer has unsuccessfully challenged one of the listed patents. Able to

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[3] The '941 patent claims escitalopram particles with an average size of forty microns—versus *three* microns for Caraco's product. Forest is playing games with the Hatch-Waxman framework because it cannot establish infringement.

avoid subsequent ANDA filers' challenges, the patentee in such cases—with a victory over the first filer on a single patent—could prevent all other generics from challenging the listed patents (and entering the market) simply by granting covenants not to sue. Such gaming of the system would gut Congress's provision for multiple challenges to the listed patents—the statutory right to obtain a decision even when the first filer's suit fails. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); 21 U.S.C. § 355(j)(5)(C). It would also be the antithesis of "enabl[ing] competitors to bring cheaper, generic . . . drugs to market as quickly as possible"—the "central purpose of the Hatch-Waxman Act." *Novartis*, 482 F.3d at 1344.[4]

After all, first filers' Paragraph IV certifications need not be correct, just complete. 21 U.S.C. § 355(j)-(5)(B)(iv)(II)(bb); Pet. App. 6a. Thus, as the D.C. Circuit observed in *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), allowing subsequent ANDA filers to use a declaratory judgment action to reach market is not only "textually persuasive," but also "a particularly appropriate solution in cases in which the second applicant has done a better job of designing around the pioneer drug manufacturer's patent than the first did: in such cases, the second applicant should find it (relatively) easy to win a declaratory judgment action against the pat-

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[4] Petitioners disclaim "gaming" the Act, noting that "avoiding the costs, uncertainty, and disruption of litigation are legitimate ends in themselves." Pet. 30. Indeed they are. But to quote petitioners, "no tears should be shed for [Forest]." *Id.* at 33. If not being "conscripted" to participate in "needless litigation" were Forest's objective (*ibid.*), it could easily be accomplished by stipulating to non-infringement and the entry of a consent decree. See Pet. App. 28a n.11.

ent-holder. [*This*] *reading thus rewards those applicants (and only those applicants) who have built a better mousetrap.*" *Id.* at 1073 (emphasis added). Caraco alleges that it has built a better mousetrap. Forest has no right to shield itself with Ivax's failure.[5]

2. Forest and its amici nonetheless complain that it is unfair for subsequent ANDA filers to be able to run off the first filer's 180-day exclusivity period before that first filer—whose own challenge to the earliest-expiring patent failed—can go to market. Pet. 33-34; Ivax Br. 3-4; Pfizer Br. 19. This argument, however, is not an argument for certiorari, but rather a policy objection to Congress's decision to permit any ANDA filer to trigger the first filer's exclusivity.

Moreover, petitioners' argument is of diminishing importance in light of the 2003 amendments to the Act. Under the pre-2003 provisions at issue here, the 180-day exclusivity period may be triggered on a *patent-by-patent* basis; but under the post-2003 law, the 180-day period applies on a *product-by-product* basis, such that *no* ANDA filer may qualify for exclusivity by challenging patents added to the Orange Book *after the first ANDA filing*. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, fewer and fewer cases will involve situations in which a first filer loses its exclusivity period on one patent, yet retains another period (based on another patent) that is put at risk in the litigation necessary for subsequent ANDA filers to reach market. For ex-

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[5] Forest asserts that *Mova* identified two distinct problems for ANDA applicants trying to reach market: the reasonable-apprehension-of-suit test *and* the case-or-controversy requirement. Pet. 4. But in fact, the problems were one and the same: the case or controversy requirement *as then applied by the Federal Circuit*. See 140 F.3d at 1073.

ample, Forest listed its '941 patent after Ivax's ANDA was filed. If the new law applied, Ivax's exclusivity would have depended entirely on its challenge to the '712 patent: Ivax would have forfeited that exclusivity period when it failed to defeat the '712 patent, and Ivax would therefore have nothing at stake in this litigation. See *id.* § 355(j)(5)(D). This case is a relic of the pre-2003 regime.

3. Petitioners say "the incentives for first filers have to be set *ex ante* behind a veil of ignorance," and they accuse the court below of allowing "other generics to take their own separate shots at piercing [Forest's] patent" based on "*ex post* knowledge that Ivax's patent litigation against Forest had failed." Pet. 32. But while the Act's incentive scheme must be analyzed apart from the outcome of particular cases, it is *Congress* that authorized all ANDA filers (not just first filers) to bring CAPCs; it is *Congress* that provided federal jurisdiction to hear such suits to the extent permitted by the Constitution; and it is *Congress* that provided for any ANDA filer's successful declaratory judgment suit to trigger the 180-day exclusivity period. Thus, insofar as the court below permitted "other generics to take their own separate shots at piercing [Forest's] patent," it was carrying out *Congress's* intent. Forest can suggest otherwise only by ignoring the Act's text.

4. Amicus Pfizer (Br. 8-10) wrongly equates the decision below with a rejected Senate bill that would have created "automatic jurisdiction" by providing that the filing of a Paragraph IV certification and the failure of the NDA holder to sue for infringement would "establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts." S. 1, 108th

Cong. § 702(c) (2003). But as the court below recognized, the *enacted* law granted jurisdiction "to the extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)), and that language expresses Congress's intent while acknowledging that "it is ultimately the province and duty of the judicial department, not Congress, to discern the limits of Article III." Pet. App. 31a n.13 (citing *Marbury* v. *Madison*, 5 U.S. (1 Cranch) 137 (1803)). The court below thus considered the specific facts here under *MedImmune*'s "all-the-circumstances test." *Id.* at 23a. Its analysis was the opposite of a formulaic, "automatic jurisdiction" approach.

C. The decision below does not conflict with this Court's decisions, and is compelled by *MedImmune*.

Forest also says the court below "ran roughshod over decisions of this Court." Pet. 15. But apart from asserting that the court contravened *Lujan* by misinterpreting the scope of the CAPC, Forest makes no attempt to demonstrate a conflict with this Court's decisions. More importantly, Forest offers no convincing argument that this Court's decision just two Terms ago in *MedImmune* does not compel the outcome below.

The plaintiff in *MedImmune* was a paid-up patent licensee who sought a declaratory judgment that the underlying patent was not infringed by the licensee's product. A fully-paid patent license is no different from a covenant not to sue—indeed, a fully-paid license *is* "an enforceable covenant not to sue." *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004). Moreover, the licensee in *MedImmune*, like Caraco here, faced "no risk" of infringement li-

ability. 549 U.S. at 128. Yet the Court found a controversy sufficient to support jurisdiction because the plaintiff had to pay royalties on a patent that it allegedly did not infringe. *Id.* at 128-130. Here, the injury is *greater*: Caraco is not merely required to pay royalties on the sale of generic Lexapro®; it is forbidden from selling generic Lexapro® *at all*, so long as there remains an unresolved dispute over infringement of the '941 patent.

Petitioners dismiss *MedImmune* by arguing that it "did not involve Hatch-Waxman" and "held only that a patent licensee could pay royalties under protest without mooting its . . . declaratory judgment action." Pet. 2, 3; accord WLF Br. 17. But in fact, the governing principles and the injury at issue—lost revenue due to a patent that the declaratory judgment plaintiff alleges is not infringed—are the same. If a paid-up license (an "enforceable covenant not to sue") did not destroy jurisdiction in *MedImmune*—where the plaintiff was free to sell its product—then Forest's covenant does not destroy jurisdiction *a fortiori*.

D. The Federal Circuit's post-*MedImmune* standing cases are not in conflict.

Lacking a serious argument that the decision below conflicts with the decisions of this Court, Forest and its amici attempt to find disarray in the Federal Circuit's standing decisions. Pet. 25; Pfizer Br. 14-19. As shown below, however, the Federal Circuit's post-*MedImmune* cases are consistent, and there is certainly no need for a second review of its standing doctrine in as many years. ROBERT L. STERN ET AL., SUPREME COURT PRACTICE § 6.37 at 459 (8th ed. 2002) ("The Court is too busy to supervise every application of its precedents to particular facts and circum-

stances, even if a given application is arguably wrong," "particularly if it has recently addressed an issue and the lower courts are just beginning to apply the rule it has declared").

1. The first note in the "cacophony" of precedent about which Forest complains is a "line of cases holding that the granting of a covenant not to sue for infringement moots a declaratory judgment action to resolve an infringement dispute." Pet. 21 n.10, 23. The cases cited, however, either have nothing to do with Hatch-Waxman, pre-date *MedImmune*, or both. Thus, they do not conflict with the decision below.

In an ordinary infringement case—where the only question is whether the plaintiff's actions expose it to liability—a covenant not to sue allows the recipient to enter the marketplace and thereby moots the case. That is why the covenants in the cases cited by Forest eliminated jurisdiction—a point the court below recognized. See Pet. App. 34a-35a.

In the Hatch-Waxman context, by contrast, a covenant not to sue does not *eliminate* the non-first filer's barrier to market entry; it *perpetuates* that injury by preventing that generic from obtaining the judgment of invalidity or non-infringement needed for FDA approval. Pet. App. 35a-36a. Thus, decisions holding that a covenant not to sue eliminates jurisdiction in a typical patent infringement case do not conflict with the ruling below.

2. Forest also relies on Federal Circuit cases holding that a plaintiff lacked an interest protected by the Patent Act. Pet. 23. Here again, however, Forest asserts rather than demonstrates that the decision below misinterpreted the scope of the CAPC. As shown above, Forest is wrong; but even if it were correct,

these cases do not remotely establish an intra-circuit conflict. Rather, they show that the circuit's *Lujan* case law is of a piece in recognizing that standing may be "founded upon a viable cause of action" (*ibid.*)—and that Forest's complaint is an (unfounded) objection to the court's reading of the CAPC.

3. Finally, Forest asserts that the Federal Circuit in *Janssen* "appeared to recognize, in conflict with the holding here, the absence of a legally cognizable injury." Pet. 24; accord Pfizer Br. 15-17. But as Forest acknowledges, *Janssen* expressly reaffirmed *Caraco*, distinguishing it on the ground that the generic manufacturer there (Apotex) "stipulated that the earliest expiring patent was valid and infringed." Pet. 24. As the court there explained:

> The key difference between *Caraco* and this case is that the harm that gave rise to the jurisdiction over the declaratory judgment claim in *Caraco* ceased to exist once Apotex stipulated to the validity, infringement, and enforceability of the [first-to-expire] patent. Therefore, *unlike Caraco, Apotex cannot claim that . . . it was being excluded from selling a noninfringing product by an invalid patent*—it stipulated to the validity of the [first-to-expire] patent. Even if Apotex successfully invalidates the [later-expiring] patents, it cannot obtain FDA approval until the expiration of the [first-to-expire] patent because of its stipulations with respect to that patent.

540 F.3d at 1361 (emphasis added).

Janssen did not question that the delayed market entry suffered by Caraco is a cognizable injury, that it is traceable to Forest, or that it will be redressed if Caraco prevails. Nor did it hold, as Forest asserts,

"that the generic's declaratory judgment claims with respect to the latter two patents were moot." Pet. 24. It simply held that a generic's CAPC challenge to one patent is not *ripe* while another, admittedly valid and infringed patent remains in force and independently precludes market entry. Because Caraco maintains that each of Forest's Lexapro® patents is invalid or not infringed, there is no conflict between *Janssen* and the decision below. See also *Minnesota Mining & Mfg. Co.* v. *Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) (a patentee's infringement suit against a generic ANDA applicant was justiciable even *after* the patentee conceded non-infringement, where the parties' disagreement over whether dismissal should be with prejudice directly affected the timing of the generic's market entry).

Forest admits that Caraco's challenge to Forest's earliest-expiring patent creates a "significant difference between *Janssen* and this case," yet says this is irrelevant because the name-brand company there argued on rehearing that the decision below should be overruled. Pet. 24-25. Any discomfort that the name-brand company may have felt about its victory in *Janssen*, however, likely stemmed from *Janssen*'s *consistency* with the decision below—such that Apotex may refile its suit when its injury from the later-expiring patents ripens.

In sum, petitioners fail to support their assertion that the Federal Circuit is "confused about the protectable-right requirement of *Lujan*." Pet. 25. The very cases on which they rely demonstrate the court's diligence in ensuring that plaintiffs have a protected legal interest related to the patent at issue.

II. The Petition Provides No Basis For Reviewing The Court Of Appeals' Holding That Caraco's Injury Is "Fairly Traceable" To Forest.

Aware that "exclusion from the generic drug market . . . is exactly the type of injury-in-fact that is sufficient to establish Article III standing" (Pet. App. 25a), Forest and its amici attempt to justify certiorari by arguing that the decision below created "tension" with other lower court rulings in failing to attribute Caraco's injury to (1) Forest's "mandatory compliance" with Hatch-Waxman, and (2) Ivax, the first filer, whose 180-day exclusivity period must run before Caraco reaches market. Pet. 16, 26-28; Ivax Br. 5-6, 10.

As shown below, however, the Act requires listing patents in the Orange Book only as a condition of receiving statutory benefits that depend on the validity and scope of those patents. Thus, it is misleading to portray the listing requirement as "mandatory." Furthermore, although the scope of Caraco's injury may be *worsened* by Ivax's 180 days of market exclusivity, it is not limited to—and does not depend on—the 180-day delay. If Caraco's product does not infringe Forest's patents, the listing of those patents *independently* causes market delay—potentially several years' worth of delay—that itself supports standing.

A. Forest's assertion that listing its patents in the Orange Book was "mandatory" mischaracterizes the Hatch-Waxman Act.

1. Like its first, Forest's second question presented—whether causation is satisfied where the injury "traces to a patent holder's compliance with a mandatory patent listing obligation" (Pet. i)—depends on a mischaracterization of the Act.

As Forest well knows from litigation over its own strategic choice *not* to list its patents in the Orange Book, the FDA's Orange Book-listing responsibilities are purely "ministerial."[6] It was Forest that took the initiative to obtain patent protection for Lexapro®, and Forest that drafted patents purportedly covering the market. Forest was thereafter "mandated" to list those patents in the Orange Book only if it wished to avail itself of Hatch-Waxman's mechanism for enforcing its monopoly—a mechanism that provides name-brand drug manufacturers substantially more protection than that enjoyed by patentees in any other context. The lawful availability of this statutory benefit (and of Forest's monopoly), however, depends on the validity and scope of the underlying patents. See 21 U.S.C. § 355(b)(1). Thus, it is misleading to say that Caraco's injury "traces to sovereign legal action," or that the decision below conflicts with lower court decisions addressing whether "but-for causation [is] sufficient to establish standing where ... the complained of conduct leads to injury only by virtue of its combination with other, more dominant causes traceable to sovereign acts." Pet. 16, 26. In sum, Forest has greatly overstated the sovereign's role in Orange Book listings and greatly understated its own.

2. Forest nonetheless attempts to gin up a conflict to support certiorari. But the two cases on which it relies (Pet. 26-27) involve highly dissimilar facts, and neither conflicts with the ruling below.

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[6] Pet. 6; see *Alphapharm Pty Ltd.* v. *Thompson*, 330 F. Supp. 2d 1 (D.D.C. 2004) (discussing Forest's strategic omission of a patent from its Orange Book-listing, rejecting an ANDA filer's complaint that the FDA was required to police such listings, and collecting authorities holding that the FDA has only a "ministerial role" in patent listings).

In *Bronson* v. *Swensen*, 500 F.3d 1099 (10th Cir. 2007), the plaintiffs attempted to challenge a criminal ban on polygamy by suing a county clerk for refusing to license a polygamous union. But as Forest notes (at 26), the plaintiffs there argued that they would have been immune from prosecution if the clerk issued them a marriage license, and the court rejected their argument because it turned on "collateral benefits" that they hoped to receive if the clerk acted in the future, rather than any injury the clerk's actions had already caused. See 500 F.3d at 1111. Here, by contrast, Caraco is suing Forest for actions it has already taken (listing its patents in the Orange Book), and injury it has already caused (throwing up a barrier to the market for generic Lexapro®). Moreover, the fact that a ruling for Caraco will have the incidental effect of triggering Ivax's 180-day exclusivity period does not diminish the fact that it will eliminate the barrier to market caused directly by Forest's patents. Thus, even setting aside the obvious factual differences between the decisions, *Bronson* does not conflict with the decision below.

Forest also asserts a conflict with *Fulani* v. *Brady*, 935 F.2d 1324 (D.C. Cir. 1991). There, a candidate excluded from a presidential debate sued the IRS to revoke the tax-exempt status of the debate's sponsor (who was not before the court), seeking to prevent it from holding the debate. See Pet. 27. But in denying standing, the court relied on the "special problems attendant upon the establishment of standing in . . . tax cases, when a litigant seeks to attack the tax exemption of a third party." 935 F.2d at 1327 (internal quotation marks omitted). Such "special problems" are absent here.

Fulani also held that intervening causes broke the chain connecting the IRS to the plaintiff's injury because, even if the court had revoked the sponsor's tax exemption, other factors still would have excluded the plaintiff from the debate. See 935 F.2d at 1329-1330. Here, by contrast, Forest's patent listing "creates an *independent* barrier to the drug market that deprives Caraco of an economic opportunity to compete," and "[i]t is well established that the creation of such barriers to compete satisfies the causation requirement." Pet. App. 27a (emphasis added).[7] Indeed, *Fulani* cuts *against* Forest's position: the court there refused to attribute causation to the sovereign when conduct by others—*parties akin to Forest*—was the true cause of injury. 935 F.2d at 1331.

3. At bottom, Forest's complaint with the Federal Circuit's traceability analysis has nothing to do with the legal standard applied by the decision below—the "but for" causation standard set forth in *Duke Power Co.* v. *Carolina Envt'l Study Group, Inc.*, 438 U.S. 59, 74 & n.26 (1978). See Pet. App. 26a. Instead, Forest is dissatisfied with how the court applied this settled principle in the Hatch-Waxman Act context. Even if Forest were correct on the merits, such an argument would not justify certiorari. But as we have shown, the court below faithfully applied this Court's jurisprudence.

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[7] Pfizer argues (at 17-18) that the decision below conflicts with *Prasco, LLC* v. *Medicis Pharm. Corp.*, 537 F.3d 1329 (Fed. Cir. 2008). But that argument depends on a flawed analogy between marking a product to provide statutory notice to potential infringers (which the *Prasco* plaintiff did *not* claim "had actually restrained its right to freely market [its product]," *id.* at 1339), and an Orange Book-listing (which immediately "creates an independent barrier to the drug market," Pet. App. 27a).

B. Caraco's injury is not limited to, and does not depend upon, the first filer's 180-day exclusivity period.

Forest and amicus Ivax also seek to justify review by arguing that the decision below created a conflict concerning the traceability standard in failing to trace Caraco's injury to Ivax's first-filer status, which they deem an "intervening cause." Pet. 16, 28; Ivax Br. 9-16. This argument lacks merit.

1. Although Caraco's ANDA may not be approved until Ivax's exclusivity period has run, that does not mean the exclusivity period is an intervening cause of Caraco's injury. Nor is this action "brought solely to spoil the first filer's exclusivity," as Pfizer asserts (at 19). To be sure, Caraco seeks to run off that 180-day delay, but also to avoid *years* of delay caused directly by the listing of Forest's patents. Whether Caraco is the first or last ANDA filer, it has a statutory right to file a CAPC challenging those patents. And a favorable ruling on Caraco's claims will clear both the (larger) barrier created by the listing of the patents and the (smaller) barrier created by the 180-day exclusivity period. In Congress's design, triggering the exclusivity period is simply an incidental effect of a successful challenge to the listed patents.

Even if the 180-day delay were not attributable to Forest's Orange Book-listing (which it is), the longer market delay caused by the listing of the patents is. For example, if Caraco defeated both the '712 and '941 patents in 2009, Caraco could enter the market in just 180 days—avoiding roughly *three years* of delay caused by the '712 patent, which otherwise would keep Caraco out of the market until 2012. This is independently sufficient to support standing.

2. Second, Ivax's argument—which acknowledges that Forest is a cause of Caraco's injury, but says "Ivax's intervening actions fundamentally sever the chain of causation"—assumes that a cause must be the *last* or *proximate* cause in the chain of causation to satisfy the causation requirement. Ivax Br. 5. But as this Court explained in *Bennett* v. *Spear*, 520 U.S. 154 (1997)—a case Forest and Ivax never cite—such a view "wrongly equates injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." *Id.* at 168-169.

Forest's actions may not be the last step in the chain of causation, but they are an independent "but for" cause of Caraco's injury—which Forest does not deny. This is more than sufficient. As then-Judge Alito once observed, "Article III standing demands a 'causal relationship,' but neither the Supreme Court nor [the Third Circuit] has ever held that but-for causation is always needed," particularly "where an effect is 'causally over-determined,' *i.e.*, where there are multiple sufficient causes." *Khodara Envt'l, Inc.* v. *Blakey*, 376 F.3d 187, 195 (3d Cir. 2004).

3. In any event, the centerpiece of Ivax's argument that there is "deep and abiding confusion" in the circuit courts over the test for traceability (Br. 7, 11-13) is a stale conflict between the D.C. and Second Circuits over particular facts presented to both courts some twenty years ago. The D.C. Circuit in *Fulani* (discussed above) rejected the Second Circuit's analysis, which had found traceability because "but for" the IRS's actions, the plaintiff's exclusion from the debate ultimately would not have occurred. *Fulani* v. *League of Women Voters*, 882 F.2d 621, 628 (2d Cir. 1989). The D.C. Circuit concluded that the Second Circuit

overlooked intervening causes better viewed as the true causes of the plaintiff's harm. See 935 F.2d at 1328-1329. But this disagreement is limited to the cases' specific facts, and does not cast doubt on the legal principle applied below. Moreover, both cases pre-date *Bennett*, which confirms that a third party who proximately causes an injury is not the only party to whom that injury may constitutionally be traced. 520 U.S. at 168-169.

Nor have the Tenth and Eleventh Circuits "thrown up their hands" on the issue of traceability. Ivax Br. 13. Rather, as the cases cited by Ivax confirm, those courts have merely explained, correctly, that the causation requirement for standing is not as stringent as the concept of proximate cause. *Nova Health Sys.* v. *Gandy*, 416 F.3d 1149, 1156 (10th Cir. 2005); *Focus on the Family* v. *Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1273 (11th Cir. 2003).

In short, consistent with the decision below (Pet. App. 26a) and the position of *both* parties in this case (see Pet. 26), all the circuits recognize that an independent "but for" cause suffices to support standing. Accordingly, there is no conflict warranting certiorari.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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