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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a form of declaratory judgment called a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C), premised on an underlying cause of action for patent infringement, remains justiciable under Article III of the Constitution after the pioneering drug company defendant holding the patent irrevocably covenants not to sue the generic drug company plaintiff for infringement of the patent at issue.

2. Whether the causation necessary to support constitutional standing exists where the claimed injury in fact traces to a patent holder's compliance with a mandatory patent listing obligation imposed by a federal statute and backed by criminal sanction.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioners hereby state that:

(1) Forest Laboratories, Inc. does not have a parent corporation, and no publicly held corporation owns 10% or more of Forest Laboratories, Inc.'s stock.

(2) Forest Laboratories Holdings, Ltd. is a wholly owned subsidiary of Forest Laboratories, Inc. Forest Laboratories, Inc. is the only publicly held corporation that owns 10% or more of Forest Laboratories Holdings, Ltd.'s stock.

(3) H. Lundbeck A/S does not have a parent corporation and no publicly held corporation owns 10% or more of H. Lundbeck A/S's stock.

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INTRODUCTION

In a case of extreme significance to the entire pharmaceutical industry, a divided panel of the Federal Circuit has interpreted the Hatch-Waxman Act[1] in a manner that upsets the careful balance Congress established in that landmark statute as between providing incentives for pioneering companies—such as Petitioner Forest (collectively Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S)—and encouraging the entry of generic enterprises—such as Respondent Caraco Pharmaceutical. In doing so, the panel has upset settled law and tugged at foundational principles of judicial power under Article III of the Constitution. Sweepingly interpreting this Court's decision two Terms ago in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), the divided panel—over a sharp dissent by Judge Daniel Friedman—did great violence to the congressionally ordained structure erected almost a generation ago by Hatch-Waxman. This will usher in an era of destabilizing and counterproductive patent litigation. Review is warranted now.

The Hatch-Waxman Act stands at the interface of the patent statutes and the approval process for pioneer and generic drugs under the food and drug laws. Notwithstanding its profound importance to the whole of the pharmaceutical industry, Hatch-

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[1] This is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Waxman has been considered by this Court only twice in the statute's 24-year lifespan.[2] Even with those two decisions, however, never before has this Court addressed a question arising under the core provisions of the Hatch-Waxman Act, let alone such a case presenting grave concerns under Article III of the Constitution.

Contrary to a large body of law holding that covenants not to sue moot suits premised on the relevant cause of action to which the covenant relates, a divided Federal Circuit panel held in this case that a new type of declaratory judgment suit created by Hatch-Waxman changed the previously clear Article III consequences of such covenants. To our knowledge, never before has a court stripped a class of litigants of their pre-existing right to avoid suit by granting an enforceable covenant not to sue—thereby functionally conscripting them as unwilling litigants—especially in the absence of a clear directive from Congress to do so.

The Federal Circuit thought its result was supported by this Court's decision two terms ago in *MedImmune*. But *MedImmune* did not involve Hatch-Waxman or its newly devised declaratory judgment suits designed to probe the boundaries of Article III. *See* 35 U.S.C. § 271(e)(5) (authorizing unique form of declaratory judgment action "to the

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[2] *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (holding preclinical studies fell within the Section 271(e)(1) exception to patent infringement for uses reasonably related to developing and submitting information to the FDA for purposes of that agency's regulation of drugs); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (considering whether this drug-based exception also applied to medical devices).

extent consistent with the Constitution"). To the contrary, *MedImmune* held only that a patent licensee could pay royalties under protest without mooting its right to bring a declaratory judgment action to determine whether the licensed patent was valid and not infringed. Nothing in that decision speaks to whether Hatch-Waxman declaratory judgment actions remain justiciable means to resolve a dispute about infringement after the patent holder grants a covenant not to sue.

For decades, the lower courts and the Food and Drug Administration ("FDA") have been grappling with the complexities Hatch-Waxman creates for patent litigation. That this Court's intervention is needed to clarify the operation of Hatch-Waxman—and the application of Article III to its regime—is loudly testified to by the invalidation of numerous Hatch-Waxman FDA regulations and interpretations leading up to the adoption of Hatch-Waxman Act-specific declaratory judgment suits.[3]

In one of the cases invalidating an FDA regulation, the D.C. Circuit suggested that declaratory judgment suits might smooth the rough edges of Hatch-Waxman. Surveying the potential pitfalls of such a purported solution, however, the court recognized:

> [Generic drug company] Mylan has also noted what may be a more serious fly in the

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[3] *See, e.g., Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (invalidating FDA's "successful defense" Hatch-Waxman regulation); *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42, 47 (D.D.C. 2000) (invalidating a different FDA Hatch-Waxman regulation construing the statutory phrase "a decision of a court").

> (patented) ointment. In order to satisfy the Constitution's case or controversy requirement, a party filing a declaratory judgment action must show that there is a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Mova, 140 F.3d at 1073 (internal quotation marks omitted).

Notwithstanding such a cautionary note, Congress decided to adopt precisely such a declaratory judgment solution in 2003 to the problems emergent in the Hatch-Waxman regime. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007) (discussing Congress's creation of the so-called "civil action to obtain patent certainty").

The *Mova* court actually saw two related "flies in the ointment" for expanded use of declaratory judgments under Hatch-Waxman: (1) the Federal Circuit's "reasonable apprehension of suit" limitation on when declaratory relief is viable in patent suits; and (2) the Article III requirement of a "Case or Controversy." *MedImmune* eliminated the former as an obstacle. 127 S. Ct. at 774 n.11. But *MedImmune* did not address, much less resolve, the entirely distinct question of the limits of Hatch-Waxman declaratory judgment actions as cabined by Article III.

Accordingly, there is an urgent need for this Court to authoritatively construe the Hatch-Waxman form of declaratory judgment action and resolve the constitutional question *MedImmune* did not resolve. This case should be chosen as the

vehicle because of its exceptional importance to the business community. At the *en banc* stage, representatives of all of the major interests regulated or touched by Hatch-Waxman asked the Federal Circuit to reconsider its erroneous decision: pioneer drug companies, a leading generic drug company, as well as pharmaceutical and biotechnical trade associations. Urging rehearing, this broad coalition of shared interests argued vigorously that the divided panel's decision radically rebalanced congressionally designed incentives to innovation and for the introduction of generic competition, while expanding the uses of Hatch-Waxman declaratory judgment suits beyond the bounds of the Constitution and of congressional intent. Indeed, one of Caraco's generic competitors was alarmed that the Federal Circuit's decision robs generic companies of the benefits Congress intended to confer on the first generic companies to challenge pioneer patents. Left unchecked, the decision will trigger a new wave of litigation the drafters of Hatch-Waxman did not remotely intend.

OPINIONS BELOW

The Federal Circuit's decision is reported at 527 F.3d 1278 (Fed. Cir. 2008) and reprinted in the Appendix ("App.") at 1a. The order of the United States District Court for the Eastern District of Michigan dismissing for lack of subject matter jurisdiction is reprinted at App. 47a.

JURISDICTION

The court of appeals rendered its decision on

April 1, 2008, and denied a timely petition for rehearing and rehearing en banc on June 24, 2008.[4] App. 45a. On September 12, 2008, Chief Justice Roberts extended the time for filing this petition to and including November 6, 2008. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Article III, Section 2, Clause 1 of the Constitution provides in relevant part that "[t]he judicial Power shall extend to all Cases, in Law and Equity [and] Controversies . . . ." Pursuant to Court Rule 14.1(f), pertinent statutory provisions are reprinted in the Appendix at 106a-110a.

STATEMENT OF THE CASE

A. Statutory Background

1. The Hatch-Waxman Act governs the approval of all drugs introduced into interstate commerce. 21 U.S.C. § 355(a). Under the Act, a pioneer drug company must obtain approval from the FDA for a new drug by submitting a New Drug Application ("NDA"). Pioneer applicants are required to file with the FDA the patent number and expiration date of all patents that claim the drug or claim a method of using the drug, if a claim of patent infringement could reasonably be asserted were the drug to be manufactured, used, or sold by another. 21 U.S.C. § 355(b)(1). The FDA is then assigned a ministerial duty to list these patents in a publication commonly

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[4] The court of appeals granted a 14-day extension of time in which to file a petition for rehearing and rehearing en banc.

known as the "Orange Book." Drugs approved by the FDA are referred to as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i). The patents listed in the Orange Book for each listed drug are referred to as "listed patents." *See* 21 C.F.R. § 314.53(f).

Failure to submit the patent information is a ground for denying NDA approval. 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, failure to provide an accurate and complete submission of patent information subjects the holder to potential criminal liability. 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004).

2. The Hatch-Waxman Act streamlines approval for generic versions of listed drugs by allowing generic drug manufacturers to submit an "Abbreviated New Drug Application" ("ANDA"). 21 U.S.C. § 355(j). If an ANDA applicant desires approval to market a generic version of the listed drug prior to expiration of a patent covering the listed drug, the ANDA applicant must include a certification that the patent covering the listed drug is invalid or not infringed by the drug that is the subject of the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is known as a "Paragraph IV" certification. Submission of a Paragraph IV certification constitutes an "artificial" act of infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 676.

The first applicant to submit an ANDA for a listed drug that includes a Paragraph IV certification against a listed patent is eligible to receive 180 days of exclusive generic marketing. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). "We will call this Edenic moment of freedom from the pressures of the

marketplace the statute's 'exclusivity period.'" *Mova*, 140 F.3d at 1064-65. The FDA may not approve any subsequent ANDA until after this 180-day exclusivity period has expired. The purpose of the exclusivity period is to incentivize generic drug companies to take on the economic and litigation risks inherent in challenging pioneer patents. *Id.* at 1075. The exclusivity period begins to run (1) when the first Paragraph IV ANDA filer commercially markets its drug (the commercial marketing trigger), or (2) on the date of a court decision holding the patent that was the subject of the certification to be invalid or not infringed (the court-judgment trigger). 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

3. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernizaton Act of 2003 ("Medicare Modernization Act"). *See supra* n.1. The Medicare Modernization Act amended the Hatch-Waxman Act by adding a new provision for a "civil action to obtain patent certainty" (hereafter "CAPC"). 21 U.S.C. § 355(j)(5)(C). Under this provision, if the holder of the NDA for a listed drug does not bring an infringement action within 45 days of receiving notice of a Paragraph IV certification for that drug, the ANDA applicant may bring a civil action for a declaratory judgment that the patents at issue are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C)(i).[5]

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[5] The Medicare Modernization Act also revised the framework under which the first Paragraph IV filer can forfeit its exclusivity period if it does not market a drug within specified periods of time. 117 Stat. at 2457-60, Section 1102. These forfeiture provisions, however, do not apply to ANDAs (such as the ANDA relevant to this case) containing Paragraph IV

The Medicare Modernization Act provides that federal courts have subject matter jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The purpose of this expression of intent was to test the boundaries of this new form of declaratory judgment against Article III. *See* App. 10a-11a (relying on statement of Senator Kennedy).

B. FACTUAL BACKGROUND

1. Forest markets the blockbuster drug Lexapro® ("Lexapro"), which is used to treat depression and generalized anxiety disorder. As part of the mandatory process for avoiding penalties and obtaining FDA approval for Lexapro, Forest filed the necessary information concerning two patents with the FDA: U.S. Patent No. Re. 34,712 (the '712 patent) and U.S. Patent No. 6,916,941 (the '941 patent).

Ivax Pharmaceuticals, Inc. ("Ivax") was the first ANDA applicant to file a Paragraph IV certification for the '712 and '941 patents. App. 12a. Ivax is therefore eligible for up to 180 days of generic market exclusivity for each patent, which will begin to run on the earlier of (1) the day Ivax begins marketing its generic drug or (2) the day a court determines that, for each such patent at issue, the patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

In response to Ivax's Paragraph IV certification,

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certifications that were filed before December 8, 2003. 117 Stat. at 2460, Section 1102(b).

which represents an act of infringement under 35 U.S.C. § 271(e)(2), Forest sued Ivax for infringement of the '712 patent. Ivax counterclaimed that the '712 patent was invalid and unenforceable. Forest prevailed completely in that litigation, obtaining a judgment that the '712 patent was valid and enforceable, along with a stipulation that Ivax's ANDA infringed that patent. App. 12a-13a. This judgment was affirmed in its entirety on appeal. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

2. In May 2006, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed ANDA 78-219 for Lexapro with the FDA. This ANDA included a Paragraph IV certification for the '712 and '941 patents. App. 15a-16a. Caraco's was the third Paragraph IV certification on the '712 patent and the seventh Paragraph IV certification on the '941 patent. In response to ANDA 78-219, Forest sued Caraco for infringement of the '712 patent (but not the '941 patent). App. 16a. That litigation is ongoing.

When Forest did not sue Caraco for infringement of the '941 patent, Caraco filed a separate action seeking a declaration that its ANDA did not infringe the '941 patent. App. 16a, 83a. Caraco did not contest the validity of the '941 patent. *Id.*

Forest then moved to dismiss Caraco's declaratory judgment action for lack of jurisdiction. App. 17a. Forest later granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent to confirm that no case or controversy existed between Forest and Caraco. The covenant provided as follows:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use sale, or offer for sale or importation of the generic products described by ANDA 78-219.

App. 19a-20a; 103a-104a.

C. PROCEEDINGS BELOW

On May 31, 2007, the district court granted Forest's motion to dismiss. App. 47a. Ruling from the bench, the court explained that because Forest had granted Caraco a covenant not to sue, Caraco suffered *no risk* of being sued for infringement and its complaint was "asking for the same relief as they already have." Hence, a controversy no longer existed under Article III, App. 77a-78a, and Caraco could not be found liable for infringement.

A divided panel of the Federal Circuit reversed. The majority held that, despite the covenant not to sue, "Caraco's declaratory judgment action presents a continuing Article III controversy" because, "in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties." App. 2a.

Addressing the three constitutional requirements for standing, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998), the Federal Circuit *first* concluded that there was an injury-in-fact because Caraco was being excluded from the drug market by the '941 patent. App. 24a-25a. Specifically, because Ivax was the first ANDA-filer

with respect to Lexapro, Caraco could not enter the market for generic Lexapro until Ivax's 180-day exclusivity period had expired. App. 26a-27a. A subsequent Paragraph IV ANDA filer such as Caraco can trigger Ivax's exclusivity period only by obtaining a judgment that the '941 patent is either invalid or not infringed. App. 27a-28a.

Second, the Federal Circuit concluded that Caraco's injury is traceable to Forest. The court stated that "Forest's listing of the '712 and '941 patents in the Orange Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both patents are invalid or not infringed by its generic drug." App. 27a. The court concluded that Forest's listing, rather than the Hatch-Waxman Act, caused Caraco's injury by preventing Caraco from entering the marketplace. *Id.*

Third, the Federal Circuit concluded that Caraco's injury is redressable by a declaratory judgment that the '941 patent is not infringed. App. 27a-28a. According to the court of appeals, "[i]f Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible." App. 28a.[6] The Federal Circuit emphasized that its

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[6] The dissenting judge took issue with that claim (see below). In addition, on September 2, 2008, after the decision here issued, a new patent issued for Lexapro—U.S. Patent No. 7,420,069 ("'069 patent"). The issuance of this new patent underscores both that Caraco is *not* close to market entry, and

reading of the purposes of the CAPC declaratory action created by Congress in 2003 was consistent with the "remarks of Senator Kennedy." App. 30a.

Addressing the other two justiciability doctrines, the Federal Circuit concluded that Caraco's declaratory judgment claim was ripe and not moot. App. 31a-36a. Although the court below conceded that Forest's covenant "would moot Caraco's case" if a threat of an infringement lawsuit "was the *only action* allegedly taken by Forest that effectively excluded Caraco from the marketplace," App. 34a (emphasis added), the panel nevertheless concluded that the covenant did not moot this case because "Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context." App. 35a.

Judge Friedman dissented. Although agreeing that Caraco's declaratory judgment claim "stems from and is based upon particular provisions of the Hatch-Waxman Act," not from any danger of damages for infringement, App. 38a, Judge Friedman maintained that Caraco's declaratory judgment claim was unripe because it was based on contingencies that may never come to pass (such as a victory by Caraco in pending patent litigation with Forest over the '712 patent). App. 40a-41a.

Judge Friedman further opined that the

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that the Federal Circuit mistakenly believed that the exclusive source of Caraco's market exclusion is Forest's purportedly discretionary decision to list the '941 patent in the Orange Book. Notably, Caraco has also failed to file a Paragraph IV certification on the '069 patent (listed September 23, 2008), though Forest has already received nine such certifications from other generic companies.

majority's "theory" was inconsistent with Congress's policy judgment to favor the *first* ANDA filer. App. 40a. In the absence of an "indication that [Senator Kennedy's] statements reflected the views of the majority of the committee or of the Senate, or the sponsors of" the Medicare Modernization Act in 2003, the dissenting judge was unwilling to conclude that such statements were an "adequate basis for determining the scope and meaning of this legislation." App. 41a. Judge Friedman also pointed out that the majority was glossing over Senator Kennedy's express caveat: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue . . . ." App. 42a.

Overall, in light of Forest's covenant not to sue, Judge Friedman would have held that, "'under all the circumstances,'" there was not a "'substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment.'" App. 41a. (quoting *MedImmune*, 127 S. Ct. at 771).

Forest sought *en banc* review or panel rehearing. Numerous amicus briefs were filed in support of rehearing.[7] Although it called for a response, the Federal Circuit ultimately denied the petition.

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[7] In addition to support by Ivax, the generic first ANDA filer, Forest had the support of pioneer drug companies Merck & Co., Inc. and Pfizer, Inc., industry trade associations the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization, and the public interest organization, the Washington Legal Foundation.

REASONS FOR GRANTING THE WRIT

The Federal Circuit's exclusive appellate jurisdiction over patent disputes, 28 U.S.C. § 1295(a)(1), (a)(4), precludes the emergence of a split among the Circuits on the questions presented. *Compare* S. Ct. R. 10(a). Nevertheless, the path by which the Federal Circuit reached its conclusion ran roughshod over decisions of this Court, while feeding circuit splits and intra-circuit divisions within the Federal Circuit itself.

Despite conceding that a viable infringement action was terminated by virtue of the covenant not to sue, *see* App. 34a, the Federal Circuit's conceptual framework required it to recast the familiar cause of action for patent infringement as a cause of action Congress has never seen fit to create. App. 35a-36a. Hatch-Waxman's operation is thus seriously distorted. Additionally, this judicial legerdemain ignores the bedrock constitutional requirement that a valid injury in fact sufficient to support standing exists only where such injury results from invasion of a "legally protected interest." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). And a "legally protected interest" here is nothing other than a congressionally created cause of action. Since at least one other Circuit has also recently announced, in derogation of *Lujan*, that the legal protectability requirement confuses standing with the merits, this Court should intervene to clarify that *Lujan* applies equally to complex regulatory regimes like Hatch-Waxman. There is no standing to press claims for redress for an injury based on a nonexistent cause of action.

The Federal Circuit decision also violated this

Court's case law by cavalierly tracing causation to actions by third parties not before the court. Here, the court of appeals held that Forest's decision to list its '941 patent in the Orange Book caused Caraco's injury. But Forest's action was mandatory, not discretionary. It is not Forest's purported listing decision (in reality a listing *obligation*) that prevented Caraco from freely entering the relevant drug market. Instead, it was Congress's decision to exclude Caraco from the market for the purpose of favoring the first ANDA filer (here Ivax) that is the cause of Caraco's claimed injury.

Other Circuits have found that no standing exists when causation for an alleged injury traces to sovereign legal action, rather than to discretionary private action. The Federal Circuit's decision in this case conflicts with those rulings.

This petition should be granted for the further reason that the decision below threatens to subvert Article III and to destabilize the careful balance Congress struck among the rights of pioneer drug companies, ANDA first filers, and subsequent ANDA filers. In its quest to serve the laudable goal of speeding the introduction of generic drugs into the market, the Federal Circuit lost sight of the stopping points in the Hatch-Waxman regime and the law of justiciability. Together, those intertwined requirements serve to protect the substantial investments in innovation pioneer companies incur, as well as the large risks ANDA first filers accept when they attempt to prove a listed patent is either invalid or not infringed.

I. CONTRARY TO SUPREME COURT AND CIRCUIT DECISIONAL LAW, THE FEDERAL CIRCUIT'S DECISION FINDS STANDING WHERE NO "LEGALLY PROTECTED INTEREST" IS AT STAKE.

1. This Court has repeatedly held that not every injury is sufficient to create a constitutional case or controversy. *See, e.g., Raines v. Byrd*, 521 U.S. 811, 825-26 (1997); *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 485-86 (1982). To the contrary, an injury must be actionable in order to give rise to constitutionally cognizable injury. This is a corollary of the point that not every "case" or "controversy" can give rise to Article III jurisdiction. Instead, "the Constitution's central mechanism of separation of powers depends largely upon common understanding of what activities are appropriate to legislatures, to executives, and to courts." *Lujan*, 504 U.S. at 559-60.

Consider *McConnell v. FEC*, 540 U.S. 93 (2003). In that case, certain plaintiffs challenged a particular provision of the Bipartisan Campaign Finance Reform Act that relaxed prior limits on "hard money" contributions. That particular subgroup of plaintiffs argued that this statutory expansion of contribution limits injured them by reducing their ability to participate in elections on an equal footing based merely on their economic status. The majority held that the plaintiffs lacked standing because the ability to compete in an election only so long as all participants have equal resources is not a "legally cognizable right." *Id.* at 227. *See also Warth v. Seldin*, 422 U.S. 490, 500 (1975) (standing "often turns on the nature and

source of the claim asserted.").

The lower courts have largely followed the instruction of this Court to test assertions of injury for standing purposes to determine if they are premised upon a valid cause of action. Take, for instance, the Fourth Circuit's opinion in *Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006). *Salt Institute* held that since the Information Quality Act created no private right of action and there was no common law cause of action to correct false information, the absence of any legally cognizable cause of action required the suit to be dismissed for want of standing. *Id.* at 158-59.[8]

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[8] *See also Pichler v. UNITE*, 542 F.3d 380, 390-92 (3d Cir. 2008) (following *Lujan*); *Neese v. Johanns*, 518 F.3d 215, 219 (4th Cir. 2008) (same); *AT&T Mobility, LLC v. National Ass'n for Stock Car Auto Racing, Inc.*, 494 F.3d 1356, 1360-62 (11th Cir. 2007) (same); *Morlan v. Universal Guar. Life Ins. Co.*, 298 F.3d 609, 621 (7th Cir. 2002) (Posner, J.) ("The possession of a legally protectable interest is a prerequisite to suing because otherwise the possessor of that interest would find himself unable to enforce it if another person, an officious intermeddler, had brought suit to enforce it (like a bounty hunter) first."); *Potthoff v. Morin*, 245 F.3d 710, 717-18 (8th Cir. 2001) ("an abstract constitutional right is not justiciable unless a legally protectible interest is at stake"); *Claybrook v. Slater*, 111 F.3d 904, 906-07, 909 (D.C. Cir. 1997) (following *Lujan*); *Alliance Against IFQs v. Brown*, 84 F.3d 343, 351-52 (9th Cir. 1996) (rejecting particular cause of action under the Magnuson Act where the fishermen's claimed injury was based on an interest belonging to the State of Alaska and thus not "an invasion of a legally protected interest . . . of the [plaintiffs]."") (internal quotation omitted); *In re Joint E. & S. Dist. Asbestos Litig.*, 78 F.3d 764, 780 (2d Cir. 1996) (following *Lujan*); *Association for Retarded Citizens of Dallas v. Dallas County Mental Health & Mental Retardation Ctr. Bd. of Trs.*, 19 F.3d 241, 244 (5th Cir. 1994) (same).

Or consider *Day v. Bond*, 500 F.3d 1127 (10th Cir. 2007), which addressed whether a Kansas law granting in-state tuition benefits to illegal aliens was preempted by a federal immigration statute. The Tenth Circuit held there was no standing because the immigration statute did not give rise to a private right of action: "The merits issue is whether [the Kansas statute] is preempted by 8 U.S.C. § 1623. The standing question is whether § 1623 creates a private cause of action. Each of these issues is separate and independent . . . ." *Id.* at 1136-39.

The same is true here. The merits question is whether Caraco's generic Lexapro would infringe Forest's '941 patent. The standing question is whether the civil action to obtain patent certainty ("CAPC") in 21 U.S.C. § 355(j)(5)(C) creates a private right of action apart from redressing disputes over infringement. The two questions are fully distinct, and the Federal Circuit was wrong to conclude that injury divorced from what is exclusively an infringement cause of action can support constitutional standing.[9]

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[9] *Day v. Bond*, which applies the analysis required by this Court's cases should be contrasted with outlier decisions, which reflect confusion about how to act on the principle that standing and merits analysis should be kept separate. *See, e.g., Club Italia Soccer & Sports Org., Inc. v. Charter Twp. of Shelby, Mich.*, 470 F.3d 286 (6th Cir. 2006). In that case, the Sixth Circuit assailed a district court decision that had held "because Plaintiff does not allege a legally protectable interest, Plaintiff does not have standing." *Id.* at 292. According to the Sixth Circuit, "[t]his conclusion improperly grafts the standing inquiry onto the merits of Plaintiff's due process claim." *Id.* Such an analysis harkens back to the outdated view that the existence of a legally protected right is irrelevant to

2. The Federal Circuit's principal error was to devise a cause of action of its own making, 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 as soon as possible. Relying on its earlier decision in *Novartis*, 482 F.3d at 1345, the Federal Circuit noted that "the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action." App. 24a. In most situations, the panel majority reasoned, the competitor of a patent holder can enter the market freely, but under Hatch-Waxman market entry must be authorized by the FDA. *See* 21 U.S.C. § 355(a). Thus, according to the panel, any action which contributes to "preventing the FDA from approving the ANDAs of generic drug manufacturers .... is a sufficient Article III injury-in-fact." App. 24a-25a.

This analysis effectively created a private right of action on the part of subsequent ANDA filers to sue for any action or inaction by a pioneering drug company that contributes to Hatch-Waxman's exclusion of generics from the marketplace while the 180-day exclusivity period for a first ANDA filer has not yet been triggered. But this newly minted, judicially created cause of action hardly resembles the civil action to obtain patent certainty created by Congress. Instead, CAPCs authorize only suits over

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demonstrating injury in fact. *Illinois. Citizens Comm. for Broad. v. FCC*, 515 F.2d 397, 413 (D.C. Cir. 1975) (separate statement by Bazelon, J., explaining why he voted in favor of en banc review). Movement in the lower courts in the direction of that discredited approach should be halted.

actual disputes concerning patent infringement or validity. 35 U.S.C. § 271(e)(5). Hence, once Forest gave Caraco a covenant not to sue, the CAPC right of action was terminated as a constitutionally cognizable controversy. *See infra* n.10. (Validity of the '941 patent was never in play because Caraco never even sought to challenge that patent on invalidity grounds.)

3. Recognizing that the covenant not to sue was problematic for its theory of standing, the Federal Circuit conceded 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 and divest the district court of Article III jurisdiction." App. 34a (emphasis added).[10] But, "in a manner that is unique to the Hatch-Waxman context," Forest injured Caraco because it listed the '941 patent with

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[10] This analytical move also allowed the panel majority to avoid running afoul of a long 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. *See Apotex, Inc. v. Pfizer, Inc.*, 125 F. App'x 987, 987 (Fed. Cir. 2005) (per curiam); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1340-41 (Fed. Cir. 2001); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1093 (1996). Indeed, just the year prior to handing down the decision in this case, the Federal Circuit had held that this line of cases did not depend on the "reasonable apprehension of suit" test disapproved in *MedImmune. Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007). Even applying *MedImmune, Benitec* reached the same essential conclusion. Yet the decision below did not distinguish, or even cite, *Benitec.*

the FDA and because it granted Caraco a covenant not to sue for infringement. App. 35a.

This ignores the critical fact that the only adverse action cognizable under the CAPC form of action in this case (where Caraco did not pursue a theory of patent invalidity) was a suit for infringement. Any other actions by Forest, no matter how injurious, cannot support standing because only a suit to declare rights in an infringement controversy can support constitutional standing. While Congress provided that the CAPC action should be interpreted as broadly as possible consistent with the bounds of Article III, *see* 35 U.S.C. § 271(e)(5), 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.

4. The only way the panel's decision here could be correct is if injury "in the air" were sufficient to support Article III jurisdiction. It is not. *In re Asbestos Litig.*, 90 F.3d 963, 1020 & n. 70 (5th Cir. 1996) (Smith, J., dissenting) ("[S]tanding analysis does not operate in a vacuum: The allegation of a cause of action frames the inquiry . . . . we must examine the pleadings to determine what cause of action the plaintiff has alleged and whether his allegations of injury, in the context of that cause of action, satisfy Article III standards.").[11] *See also*

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[11] The petition for certiorari was granted in *In re Asbestos Litigation*, with the decision being vacated and remanded for reconsideration on statutory grounds in light of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). After remand, reversal by *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), of

International Primate Prot. League v. Administrators of Tulane Educ. Fund, 500 U.S. 72, 77 (1991) ("[S]tanding is gauged by the specific common-law, statutory or constitutional claims that a party presents."); *Catholic Social Serv. v. Shalala*, 12 F.3d 1123, 1125 (D.C. Cir. 1994) (similar); *Lujan*, 504 U.S. at 580 (Kennedy, J., concurring) ("In my view, Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before . . . .").

5. The decision below also is in conflict with the Federal Circuit's prior decisions. *See Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340-41 (Fed. Cir. 2007) (party that held insufficient rights in a patent lacked standing to sue because "[the plaintiff] is not the party to which the statutes grant judicial relief . . . . [the plaintiff] suffers no legal injury in fact to the patent's exclusionary rights.") (citing *Warth*); *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003) (plaintiff lacked Article III standing because it had insufficient legal interest in the patent to be considered "the patentee" under the Patent Act). Indeed, the author of this very opinion previously recognized that standing can only be founded upon the assertion of a viable cause of action. *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001) (Gajarsa, J.) (relying on *Lujan*, stating "TCI-California is correct in its assertion that Article III standing to sue in this case derives solely from

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the Fifth Circuit majority, fully vindicated the pre- and post-remand dissents of Judge Smith, albeit on grounds of a lack of "statutory standing." *Id.* at 831.

the Patent Act.").

In like manner, in a decision released just this September addressing a fact pattern very similar to this case, a *different* panel of the Federal Circuit appeared to recognize, in conflict with the holding here, the absence of a legally cognizable injury. In *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), the innovator pharmaceutical company (Janssen) listed three patents in the Orange Book and successfully defended against challenges brought by the first Paragraph IV ANDA filers to the earliest-expiring patent. *Id.* at 1357-58. In subsequent litigation between the innovator and another generic (Apotex), the generic stipulated that the earliest-expiring patent was valid and not infringed, and the innovator gave the generic a covenant not to sue on the other two patents. *Id.* at 1358-59. In that case, the Federal Circuit held that the generic's declaratory judgment claims with respect to the latter two patents were moot. *Id.* at 1360-61. The court stated that "Apotex's inability to launch its generic . . . because of Teva's 180-day exclusivity period *is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act.*" *Id.* (emphasis added).

The only significant difference between *Janssen* and this case—and the basis on which the *Janssen* panel purported to distinguish this case—is that Forest and Caraco are litigating Forest's earliest-expiring patent on Lexapro—the '712 patent—in a separate action. *Id.* at 1361. In petition-for-rehearing briefing, neither side in the *Janssen* litigation found this distinction entirely tenable. The losing generic company, of course, protested that

the instant case and *Janssen* were indistinguishable. But even prevailing party Janssen, the innovator drug company, argued in the alternative that the Federal Circuit decision here should be overruled in *Janssen* because both this suit and that suit are beyond the reach of Article III. Nevertheless, the Federal Circuit denied Apotex's petition for rehearing on October 29, 2008.

The ineluctable conclusion to be drawn from this cacophony of Federal Circuit precedent is that the court is deeply confused about the protectable-right requirement of *Lujan*, both generally and in the vitally important context of the Hatch-Waxman Act. Even when the Federal Circuit acknowledges the importance of legally protected rights to standing issues, it does not necessarily deploy the correct analysis. *See Willis v. GAO*, 448 F.3d 1341, 1349 (Fed. Cir. 2006) (only client had legally protected right to statutory attorney's fees and hence "the attorney [seeking to recover fees] fails to satisfy the requirements of *prudential standing*") (emphasis added). The emphasis in *McConnell*, *Lujan*, *International Primate*, and *Warth* on legally protected rights was *not* premised on prudential standing. To the contrary, it was premised upon the foundational requirements of Article III.

II. CONTRARY TO SUPREME COURT AND CIRCUIT LAW, THE FEDERAL CIRCUIT'S DECISION FINDS STANDING WHERE CAUSATION IS FAIRLY TRACEABLE ONLY TO CAUSES BEYOND THE DEFENDANTS' CONTROL.

1. The Federal Circuit held that Caraco's injury is "fairly traceable" to Forest because "if Forest had not listed its '712 and '941 patents in the FDA's

Orange Book as valid patents covering the drug described in its NDA for Lexapro, then [the Hatch-Waxman Act] would not independently delay Caraco's ANDA from being approved by the FDA." App. 26a. "Such but-for causation," the court concluded, "is sufficient to satisfy the traceability requirement of Article III standing." *Id.* (citing *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26 (1978)).

In the full context of this case, however, the Federal Circuit's reliance on "but-for" causation is in tension with decisions of the Tenth Circuit and D.C. Circuit. *See Bronson v. Swensen*, 500 F.3d 1099 (10th Cir. 2007); *Fulani v. Brady*, 935 F.2d 1324 (D.C. Cir. 1991). Those courts have rejected but-for causation as sufficient to establish standing where, as here, the complained-of conduct leads to injury only by virtue of its combination with other, more dominant causes traceable to sovereign acts.

In *Bronson*, the plaintiffs filed a civil rights action against a county clerk for refusing to issue a marriage license that would have resulted in a polygamous union in violation of state criminal law. 500 F.3d at 1101. Although conceding that the clerk had no power to initiate criminal prosecutions, the plaintiffs argued that their injury was traceable to the county clerk because if the clerk issued a marriage license, then they arguably would be free from fear of criminal prosecution. *Id.* at 1110-11. The Tenth Circuit rejected plaintiffs' arguments because they were based on allegations that they would receive collateral benefits (freedom from criminal prosecution) if the clerk granted the license, not on any injury caused by the clerk. *Id.* at 1111.

Likewise, in *Fulani*, a minor-party presidential

candidate brought an action against the Internal Revenue Service challenging the tax-exempt status of the Commission for Presidential Debates, which had excluded her from the 1988 presidential debates. 935 F.2d at 1325. Under Federal Election Commission rules, the Commission could sponsor the debate only if it received tax-exempt status. *Id.* at 1325, 1330. The D.C. Circuit concluded that Fulani lacked standing to bring her challenge because the "IRS's actions caused her alleged injury only due to other intervening causal factors," including the FEC's regulations and Commission's actions. *Id.* at 1331. Even though Fulani's suit against the IRS, if successful, would have resulted in the Commission no longer being able to hold debates that excluded her as a participant, the D.C. Circuit rejected the argument that because Fulani's injury might be redressed by judgment against the IRS, the IRS must be deemed the cause of her injury.

In this case, by contrast, the Federal Circuit has taken the position that because Caraco's victory in a declaratory judgment suit against Forest could ameliorate Caraco's injury of delay in market entry, Forest's actions to grant a covenant not to sue and its compliance with the Hatch-Waxman Act listing mandate must be the causes of Caraco's injury. But the Federal Circuit's holding that a party's mandatory compliance with a statute can give rise to actionable injury by another party cannot be squared with the judgments of the Tenth and D.C. Circuits. Those courts properly recognize that Article III standing requires that the injury that is the subject of the suit be caused by the defendant that the plaintiff is suing. *Accord Lujan*, 504 U.S. at 560-61 ("[T]here must be a causal connection between the

injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action *of the defendant*, and not . . . th[e] result [of] the independent action of some third party not before the court.'") (emphasis added) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)).

In *Allen v. Wright*, 468 U.S. 737 (1984), *Simon*, and *Warth*, this Court held that the plaintiffs' injuries were not "fairly traceable" to the defendants where the chain of causation was broken by the actions of independent third parties. In *Allen* and *Simon*, the plaintiffs sued officers of the IRS, alleging that the Service's unlawful grants of tax exemptions to third parties led to the plaintiffs suffering injuries at the hands of the third parties. *See Allen*, 468 U.S. at 746 (explaining the chain of causation alleged in the complaint); *Simon*, 426 U.S. at 32-33 (same). In *Warth*, the plaintiffs alleged that a city's zoning ordinance led to their injury by making it more difficult for third parties to confer benefits on them. 422 U.S. at 495-97.

2. There is simply no basis for concluding that Forest's actions are the real cause of the injury the Federal Circuit posited Caraco suffers—exclusion from the market for generic Lexapro. This is true for several reasons.

First, the primary source of Caraco's inability to sell generic Lexapro is the Hatch-Waxman Act bar blocking the FDA from approving Caraco's ANDA until 180 days after (1) Ivax begins marketing its generic products; or (2) for each patent at issue, issuance of a decision of non-infringement or invalidity. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). That obstacle, however, is not of Forest's making. Rather,

it is the result of Congress's decision to encourage early challenges to patents listed in the Orange Book by rewarding the first generic to file a Paragraph IV certification, which inevitably comes at the expense of subsequent-filer generics. In this case, Ivax was the *first* filer on the '941 patent. Caraco was the *seventh*. Hence, by congressional decree, Caraco must wait until Ivax's exclusivity period has elapsed.

Second, Forest's challenged conduct—the listing of its patents in the Orange Book—is required by statute. 21 U.S.C. § 355(b)(1). Had Forest failed to list either of its patents, it would be subject to various penalties, including withdrawal of its own NDA approval and authorization to sell. *See* 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, the Hatch-Waxman listing obligation is backed forcefully by potential criminal sanctions. *See* 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004) (failure to provide an accurate and complete submission of patent information in an NDA subjects the holder to criminal liability for perjury). Thus, to the extent that Forest's listing of its patents caused Caraco's injury, that is the consequence of yet another set of choices made by Congress, or by the FDA pursuant to delegated authority under Hatch-Waxman.

Third, as explained in Section I, *supra*, even if Forest's decision to avoid the expense and disruption of litigation concerning the '941 patent were a minor contributing cause of injury to Caraco, such a cause is not legally actionable. The reason is that Forest has no enforceable duty to refrain from granting irrevocable covenants not to sue and because, on the flip side of that point, Caraco has no valid cause of action to force Forest to retract its covenant.

3. The Federal Circuit majority accuses Forest of "gaming" the Hatch-Waxman Act system. App. 9a. Not so. It is wrong to presume that every decision by a pioneer drug holder to litigate regarding only one of its patents constitutes strategic behavior. Avoiding the costs, uncertainty, and disruption of litigation are legitimate ends in themselves.

Apparently, the court below thought that it was empowered to assume that any action by a pioneer drug company which might contribute to the delay of the introduction of generic competition violated Congress's purposes in enacting Hatch-Waxman and the Medicare Modernization Act amendments. App. 8a (discussing a pioneer drug company's "strong incentive to avoid litigation" so as to delay the onset of a first ANDA filer's exclusivity period).

But "no legislation pursues its purposes at all costs. . . . [I]t frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 525-526, (1987) (per curiam). The Federal Circuit majority itself recognized this when it pointed out that the purpose of Hatch-Waxman was to *balance* the interests of pioneer and generic drug companies. App. 3a. But by elevating a minor cause and ignoring the more dominant causes of the Hatch-Waxman restriction on market entry and the Act's requirement to list patents in the Orange Book, the majority below took it upon itself to rebalance Congress's policy choices as inherent in the limits on the cause of action for infringement as established in the CAPC form of suit. Or, as dissenting Judge Friedman recognized, "[t]o the extent that Congress may conclude that particular judicial interpretations

of the Act thwart the purposes of the legislation, it is for Congress, not this court, to make whatever changes in the Act it deems appropriate." App. 42a.

III. THE ISSUES IN THIS CASE ARE EXCEPTIONALLY IMPORTANT TO PHARMACEUTICAL INNOVATION AND THE NATION'S ECONOMY.

1. The Federal Circuit's decision threatens to disrupt the careful balance of incentives Congress created to ensure that the public will benefit from receiving the most pharmaceutical innovation at the lowest cost. The divided panel's decision creates a precedent of generalized significance concerning the effect of covenants not to sue on all future CAPC actions under the Hatch-Waxman Act, and thus will apply to all relevant patent disputes in this area. 28 U.S.C. § 1295(a)(1), (a)(4); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829 (2002).

The landmark Hatch-Waxman legislation amended both the food and drug and the patent laws to strike a careful balance between two competing policy objectives: (1) inducing innovators to make the investments necessary to develop new drugs, and (2) enabling generics to bring lower-cost versions of those drugs to market in a timely fashion. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

In furtherance of the latter objective, Congress encouraged generics to challenge innovators' patents as soon as possible by offering the incentive of 180 days of generic market exclusivity to the *first* ANDA

filer. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Importantly, Congress chose to protect the 180-day exclusivity period by forbidding the FDA from approving the applications of other generics. *Id.*

In the case at hand, the panel majority may have chosen to discount the value Congress placed upon incentives to first filers because it had the *ex post* knowledge that Ivax's patent litigation against Forest had failed. But that kind of *post hoc* analysis is improper because the incentives for first filers to bring patent challenges inevitably have to be set *ex ante* behind a veil of ignorance as to whether particular patent litigation will succeed or fail. From a "Monday-morning quarterback" perspective, it is easy to see why a court might want to give a chance to other generics to take their own separate shots at piercing a patent. But it frustrates the will of Congress to do anything other than faithfully and vigorously enforce the 180-day market exclusion the Article I branch established to incentivize first filers to mount patent challenges. *Cf. Hughes Aircraft Co. v. Jacobsen*, 525 U.S. 432, 447 (1999) ("[B]ecause ERISA is a comprehensive and reticulated statute, and is enormously complex and detailed, it should not be supplemented with extratextual remedies.") (citations and internal quotation marks omitted).

In this case, Ivax lunged at the incentive Congress established and assumed the substantial risk of bringing the *first* challenge to Forest's patents. Caraco, by contrast, choose to fall back deep into the queue. It waited a year to become the *seventh* ANDA filer to challenge Forest's '941 patent. Given Ivax's initiative and Caraco's opportunistic choice of waiting to see how infringement litigation between Forest and Ivax played out, Forest's

willingness to avoid further litigation by granting a covenant not to sue, together with the limited cause of action for infringement or invalidity created in the Medicare Modernization Act, add up to the nonexistence of an Article III controversy. In short, no tears should be shed for Caraco. Had it been the first ANDA filer, it would not be in a position where it lacks a viable cause of action and thus constitutional standing.

2. If the Federal Circuit's decision is allowed to stand, it will cause serious marketplace harm, diluting the incentives Congress created for both innovators and first-out-of-the-gate generics.

First, innovators like Forest will be forced to defend themselves in needless litigation against generics they have already promised not to sue. Indeed, the Federal Circuit never considered the practical implications of its holding. Can Forest be conscripted against its will to litigate against Caraco? Does interpreting the statute to have the effect of drafting Forest into an involuntary litigation role raise constitutional questions? Are there interpretations of Hatch Waxman that would avoid such an unprecedented interference in private litigation, in the fashion of *Ashwander v. TVA*, 297 U.S. 288, 348 (1936) (Brandeis, J.) ("[I]t is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the [constitutional] question may be avoided")? No satisfactory answers were provided (or even ventured) to these questions by the Federal Circuit.

Second, the boldest risk-taking generics most favored by Congress, such as Ivax, will witness a severe reduction of their incentives to engage in

costly patent challenges. As it explained in its *amicus* brief in support of rehearing below, "Ivax has a strong interest in protecting the exclusivity incentive against unproductive and self-serving challenges like Caraco's." Br. Amicus Curiae of Ivax Pharm., Inc. in Support of Rehearing at 3. "If generic companies can bring declaratory judgment actions directed to patents that they have no risk of infringing, and by so doing eliminate a competitor's marketing exclusivity, they will do so at every opportunity." *Id.* at 2-3. The serious practical problem, which Congress wisely calibrated the Hatch-Waxman regime to account for, is that a sidelines-sitting opportunist like Caraco has far less "skin in the game" than an incentivized challenger like Ivax.

Indeed, the balance of incentives Congress offered to innovators and generics is critically important to the public interest. In 2007, the American pharmaceutical industry spent an estimated $58.8 billion on research and development of new drugs. *See* Pharmaceutical Research & Manufacturers of America, PHARMACEUTICAL INDUSTRY PROFILE 2 (2008). On the other side of the scales, a 1998 study estimated that generic drugs save consumers between $8 and 10 billion per year. *See* Congressional Budget Office, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 31 (1998). In a poor exchange, the Federal Circuit's decision weakens the incentives in both sectors of the pharmaceutical industry so as to reward laggard generics. This is irrational and contrary to Congress's democratic choices (which are protected by the bulwark of Article III). Most

importantly, in undermining the incentives both to the development of new pioneering drugs and efforts by bold generics to weed out weak patents from the system, the divided panel decision below will inexorably inflict net harm on consumers and the public health.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted.

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