

No. 10- **101070** **FEB 25 2011**

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IN THE

**Supreme Court of the United States**

EISAI CO. LTD. AND EISAI MEDICAL RESEARCH, INC.,  
*Petitioners,*

v.

TEVA PHARMACEUTICALS USA, INC., through its  
GATE PHARMACEUTICALS Division,  
*Respondent.*

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

**PETITION FOR A WRIT OF CERTIORARI**

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## **QUESTION PRESENTED**

When a case becomes moot by the happenstance of a third party's independent action after the court of appeals issues a judgment but while a petition for rehearing is still pending, should the court of appeals vacate the judgment upon the request of the aggrieved party?

## **CORPORATE DISCLOSURE STATEMENT**

On October 1, 2009, Eisai Medical Research, Inc. was merged into Eisai Inc. Eisai Inc. is wholly owned by Eisai Corporation of North America, which is wholly owned by Eisai Co., Ltd. There are no parent corporations or publicly held companies that own 10% or more of the stock of Eisai Co., Ltd.

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## OPINIONS AND ORDERS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is reported at 620 F.3d 1341 (Fed. Cir. 2010) and reproduced in the Petition Appendix (“App.”) at 1a-17a. The order denying petitioner’s motion for vacatur on the grounds of mootness is reproduced at App. 18a-19a. The opinion of the United States District Court for the District of New Jersey is unreported, but is reproduced at App. 22a-48a.

## JURISDICTION

The judgment of the Federal Circuit was entered on October 6, 2010. The order denying the petition for rehearing was entered on December 6, 2010. App. 52a-53a. The order denying petitioners’ motion for vacatur of the judgment on the grounds of mootness was issued on December 10, 2010. App. 18a-19a. The Federal Circuit issued its mandate on December 13, 2010. App. 20a-21a.

This petition is timely filed within 90 days of the denial of rehearing. The district court had jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a); *see, e.g., United States v. Ruiz*, 536 U.S. 622, 628 (2002) (“a federal court always has jurisdiction to determine its own jurisdiction”), and the court of appeals had jurisdiction when the appeal was filed pursuant to 28 U.S.C. § 1295(a)(1). This Court has jurisdiction under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant provisions of Article III, Section 2, Clause 1 of the United States Constitution, the Declaratory Judgment Act, 28 U.S.C. § 2201(a), and the Hatch-Waxman Act,<sup>1</sup> 21 U.S.C. § 355 (2000 & Supp. II 2003), 35 U.S.C. § 271(e), are reproduced at App. 54a-104a.

### STATEMENT OF THE CASE

#### A. Introduction

In 2008, respondent Teva Pharmaceuticals USA, Inc. (“Teva”) filed an action for declaratory judgment that its proposed generic product did not infringe four patents issued to petitioners Eisai Medical Research, Inc. and Eisai Co., Ltd. (together, “Eisai”) that the Federal Drug Administration (“FDA”) lists as associated with Eisai’s pioneer drug Aricept®. Teva did so to trigger the period of exclusive generic sales that the Hatch-Waxman Act, 21 U.S.C. § 355, granted to its non-party competitor, Ranbaxy Laboratories, Ltd. (“Ranbaxy”). Triggering Ranbaxy’s period of exclusivity would potentially hasten the date on which Teva could enter the market with its own generic product.

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<sup>1</sup> The Hatch-Waxman Act 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) (codified at 21 U.S.C. §§ 355, 360cc, 35 U.S.C. §§ 156, 271, 282), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. L. No. 108-173, 117 Stat. 2066 (2003).

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In a decision of wide-ranging significance to the pharmaceutical industry, the Federal Circuit held that, under the Hatch-Waxman Act, a generic manufacturer may seek a declaratory judgment of noninfringement against a patentee even though the patentee either disclaimed the relevant patents or gave the challenger a covenant-not-to-sue, and there was no adversity with respect to the patents between the parties. The Federal Circuit thus effectively endorsed advisory opinions by district courts concerning the validity and infringement of patents that are no longer the property of the patentee or cannot otherwise be asserted against the declaratory-judgment plaintiff. The court of appeals justified Article III subject matter jurisdiction in the absence of any controversy between the parties over patent infringement or validity solely on the basis that a declaratory judgment would be useful to the generic manufacturer in requesting that the FDA remove a statutory right of exclusivity granted by the Hatch-Waxman Act to a non-party. The Federal Circuit wrongly reasoned that this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), required this expansive interpretation of federal court jurisdiction under Article III of the Constitution.

Eisai filed a petition for rehearing and for rehearing *en banc*, and prepared a petition for certiorari to this Court in the event that rehearing was denied. During the pendency of the rehearing petition, Ranbaxy on November 30, 2010, began selling its generic version of Aricept® in the United States. Ranbaxy's commercial launch triggered its period of generic market exclusivity under the Hatch-Waxman Act. The ability to trigger non-party

Ranbaxy's exclusivity period was the exact relief that Teva had sought in its declaratory judgment action against Eisai for patent noninfringement; indeed, Teva had contended that a declaratory judgment was *necessary* to trigger Ranbaxy's exclusivity period.

Thus, based on Ranbaxy's triggering of its exclusivity period, both parties informed the Federal Circuit that the action was moot, and Eisai requested that the court of appeals vacate its opinion and judgment in light of mootness. The Federal Circuit, however, denied the petition for rehearing on December 6, 2010, App.52a-53a, and then denied Eisai's motion for vacatur on December 10, 2010. App. 18a-19a. The Federal Circuit then issued a mandate to the district court based on its judgment that had reversed a finding of no subject matter jurisdiction, thereby ordering the (now moot) declaratory judgment action to proceed on the merits.

The Federal Circuit's denial of vacatur is directly contrary to the line of this Court's precedents beginning with *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), that hold that courts should vacate judgments in a case that becomes moot unless the moving party's actions make vacatur inequitable. Eisai is unfairly saddled with a preclusive judgment of suspect merit in an important area of federal jurisprudence even though mootness prevents further review by this Court. This is precisely the wrong that the *Munsingwear* doctrine is designed to prevent. This Court should follow its customary practice of vacating court of appeals judgments that become moot after judgment, or alternatively set the petition for argument to resolve an entrenched and acknowledged split of authority over whether vacatur

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should be denied simply because the court of appeals has already issued its judgment.

## **B. The Hatch-Waxman Statutory Regime**

The Hatch-Waxman Act, 21 U.S.C. § 355, governs the Food and Drug Administration's ("FDA's") approval of pioneering and generic drugs. The Hatch-Waxman Act seeks to balance two competing goals: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Under the Hatch-Waxman Act, a pioneer drug company seeking to market a new drug must submit a New Drug Application ("NDA") to the FDA. 21 U.S.C. § 355(a), (b). The NDA must identify all patents covering the drug or methods of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1), (c)(2). A failure to submit accurate and complete patent information is a ground for denying NDA approval, and may subject the applicant to a range of penalties, including criminal liability. 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.53(b), (c); 21 C.F.R. § 314.150(a)(2)(v). The FDA lists these patents in a publication titled the *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the "Orange Book." 21 U.S.C. §§ 355(b)(1), (j)(2)(A)(ii), (j)(2)(A)(iii); *see also* Office of Generic Drugs, U.S. Dep't of Health & Human Servs., *Approved Drug Products with Therapeutic Equivalence Evaluations* (30th ed. 2010), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

The Hatch-Waxman Act also streamlines approval for generic drugs by permitting the generic manufacturer to submit an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). In an ANDA, a generic drug manufacturer that can show bioequivalence of the generic and pioneer drugs may rely on the safety and efficacy data generated by the pioneer manufacturer (which is usually a result of extensive and costly research). 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv), (j)(8)(B).

A generic manufacturer that takes advantage of the Hatch-Waxman Act's abbreviated procedure must include in the ANDA one of the following certifications as to each patent listed in the Orange Book for the pioneer drug:

- (I) that such patent information has not been filed;
- (II) that such patent has expired;
- (III) of the date on which such patent will expire; or
- (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). These certifications are known as Paragraph I, II, III, and IV certifications, respectively.

A Paragraph III certification indicates that the generic manufacturer intends to respect that patent's validity. The FDA will then wait until the expiration of that patent before approving the ANDA. By contrast, if a generic manufacturer seeks to market a generic product before the expiration of a listed

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patent covering that drug, the manufacturer must file a Paragraph IV certification.

A generic manufacturer that has filed a Paragraph IV certification must provide to the pioneer manufacturer “a detailed statement of the factual and legal basis of the opinion of the [ANDA] applicant that the patent is invalid or will not be infringed.” 21 U.S.C. § 355(j)(2)(B)(iv)(II). Upon receiving this notice, the pioneer manufacturer may sue the generic company for patent infringement. 35 U.S.C. § 271(e)(2).<sup>2</sup>

To provide an incentive for the early development of generic products, the Hatch-Waxman Act grants the first ANDA applicant to file a Paragraph IV certification a 180-day period of exclusive rights to market generic products. 21 U.S.C. § 355(j)(5)(B)(iv). During this period, the FDA may not approve ANDAs later filed by a competing generic manufacturer based on the same NDA. *Id.*; *see also Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 122 (D.C. Cir. 2006).

The generic first-filer’s 180-day exclusivity period as to its competitor generics may be triggered by either of two events: (1) the first-filer’s commercial marketing of its generic drug, or (2) a final judicial decision finding the patent subject to the Paragraph IV certification invalid or not infringed.

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<sup>2</sup> The Hatch-Waxman Act contains an incentive for the pioneer drug manufacturer to file a lawsuit within 45 days; such an early filing automatically stays the FDA’s approval of the generic company’s ANDA for 30 months or until an adverse judgment is entered, whichever occurs first. 21 U.S.C. § 355 (j)(5)(B)(iii).

21 U.S.C. § 355(j)(5)(B)(iv).<sup>3</sup> Once the exclusivity period has run or been forfeited, the subsequent ANDA applicants may start marketing their generic equivalents.

The Hatch-Waxman Act provides that a civil action under 28 U.S.C. § 2201 may be filed for “a declaratory judgment that the [listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval.” 21 U.S.C. § 355(j)(5)(C)(i)(II). The Paragraph IV ANDA applicant may not file this action prior to 45 days from the patent owner’s receipt of a notice of the Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C)(i). In authorizing this “[c]ivil action to obtain patent certainty,” 21 U.S.C. § 355(j)(5)(C), Congress specified that federal courts shall have subject matter jurisdiction with respect to such declaratory action only “to the extent consistent with the Constitution.” 35 U.S.C. § 271(e)(5).

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<sup>3</sup> In December 2003, Congress amended the Hatch-Waxman Act’s provisions governing the manner of commencement of the 180-day exclusivity period through the enactment of the MMA. See Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60 (codified at 21 U.S.C. § 355(j)(5)(D)). Under the post-2003 regime, the 180-day exclusivity period is triggered only by the first-filer’s commercial marketing, but the first ANDA filer can forfeit that exclusivity period if it fails to market its drug within a certain time period after a final judicial decision finding the patent subject to the Paragraph IV certification invalid or not infringed. 21 U.S.C. § 355(j)(5)(D). The present case applied the original, pre-2003 form of the 180-day exclusivity trigger. § 1102(b), 117 Stat. at 2460. The petition appendix reproduces the codified pre-2003 version of 21 U.S.C. § 355. See App. 54a-96a.



## C. Statement of Facts

### 1. Patents

In connection with its NDA for Aricept®, Eisai submitted five patents, which the FDA listed in the Orange Book. U.S. Patent No. 4,895,841 (“the ’841 patent”) was directed to donepezil, the active pharmaceutical ingredient in Aricept®, and its use to treat Alzheimer’s disease. The other four listed patents were the subject of Teva’s declaratory judgment action: U.S. Patent Nos. 5,985,864 (“’864 patent”), 6,140,321 (“’321 patent”), 6,245,911 (“’911 patent”), and 6,372,760 (“’760 patent”) (collectively, “the DJ patents”). The ’321, ’864, and ’911 patents were later patents directed to various “polymorph” (crystalline) forms of donepezil. The ’760 patent was a later patent directed to a formulation including donepezil.

The ’841 patent expired on November 25, 2010. With respect to the DJ patents, Eisai had disclaimed the ’321 and ’864 patents pursuant to 35 U.S.C. § 253 on May 22, 2006, and May 1, 2007, respectively, over a year before Teva filed its declaratory judgment action. A statutory disclaimer has the effect of cancelling the patent claims *ab initio*, with the result that the claims cannot be reissued or enforced. App. 7a-8a (citing *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996)); 35 U.S.C. § 253 (a disclaimer shall “be considered as part of the original patent”).

As to the remaining two DJ patents (the ’911 patent and the ’760 patent), Teva sought and Eisai granted a covenant-not-to-sue. App. 8a. Under the covenant, Eisai unconditionally agreed not to assert the ’911 and ’760 patents against Teva with respect to

any formulation of generic donepezil described in Teva's ANDAs. *Id.* Eisai gave Teva this covenant on May 20, 2008, reaffirming it on October 2, 2008. The '911 patent expires on December 1, 2018, and the '760 patent expires on March 31, 2019.

## **2. Factual Background**

**1. Eisai's NDA for Aricept®.** Eisai is a holder of an FDA-approved NDA for Aricept® (donepezil hydrochloride). The FDA approved Eisai's NDA on November 25, 1996.

**2. Ranbaxy's First-Filed ANDA.** In August 2003, Ranbaxy Laboratories Ltd., a non-party generic drug company, filed the first ANDA for generic donepezil. App. 5a. Ranbaxy made a Paragraph III certification as to the '841 patent, thereby indicating that it would respect the patent and not seek to market its generic equivalent until that patent expired. Ranbaxy submitted Paragraph IV certifications as to the DJ patents, indicating its opinion that the four patents were not infringed by Ranbaxy's generic donepezil product. *Id.* By filing the first Paragraph IV certification as to the DJ patents, Ranbaxy became eligible for the 180-day exclusivity period upon the FDA's approval of its ANDA. 21 U.S.C. § 355(j)(5)(B)(iv). Eisai did not file any suit for patent infringement against Ranbaxy.

**3. Teva's First ANDA.** Teva was a subsequent filer of two separate ANDAs for generic donepezil. Teva filed its first ANDA in October 2004. Like Ranbaxy, Teva's original ANDA included a Paragraph III certification respecting the '841 patent and Paragraph IV certifications with respect to the

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DJ patents. App. 6a. Eisai did not sue Teva for infringement.

In October 2005, Teva amended its ANDA, changing the '841 patent's certification from Paragraph III to Paragraph IV, claiming that donepezil had been obvious and continuing to make Paragraph IV certifications as to the DJ patents. *Id.*

Upon receiving notice of Teva's Paragraph IV certifications, Eisai sued Teva for infringement only of the '841 patent under 35 U.S.C. § 271(e)(2). Eisai again did not assert infringement of the DJ patents.

**4. Teva's Second ANDA.** In July 2005, Teva filed a second ANDA for a generic equivalent to Aricept®. In November 2005, Teva re-filed this ANDA in the name of its unincorporated division, Gate Pharmaceuticals. Teva asserted that its second ANDA specified a different supplier of donepezil than Teva's first ANDA.

As filed in 2005, Teva's second ANDA contained only Paragraph III certifications for all five of Eisai's listed patents. App. 6a. Two years later, in October 2007, Teva amended its second ANDA changing all five certifications to Paragraph IV certifications. *Id.* Upon receiving notice of these certifications, Eisai commenced another suit against Teva for infringement only of the '841 patent. *Id.* As with the prior lawsuit, Eisai did not sue Teva on the DJ patents. The two actions were then consolidated. *Id.*

**5. Eisai's '841 Patent Infringement Action and the Injunction Against Teva.** During the litigation over the '841 patent, Teva stipulated that its generic forms of donepezil infringed the '841 patent, but asserted that the patent was

unenforceable due to alleged inequitable conduct by Eisai. App. 6a-7a, 30a-32a.

In late 2007, Teva informed Eisai that it planned to launch generic donepezil despite the pending litigation upon the FDA's approval of Teva's first ANDA. App. 30a-31a. Eisai sought and obtained a preliminary injunction against Teva. App. 7a; *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 05-5727, 2008 WL 1722098, at \*13 (D.N.J. Mar. 28, 2008). The injunction barred Teva, including its Gate division, from marketing any drug containing donepezil as claimed in the '841 patent. App. 7a. Accordingly, Teva was prohibited from selling donepezil under any ANDA until expiration of the patent on November 25, 2010.

In July 2010, with the district court's approval, Teva entered into a stipulation with Eisai, agreeing that it would take no further action in the litigation and that the preliminary injunction would "remain in effect" until the '841 patent expires. App. 14a n.4.

**6. Teva's Declaratory Judgment Action.** After being enjoined, in May 2008, some three years after Teva had first filed Paragraph IV certifications as to the DJ patents, Teva filed the instant declaratory-judgment action, seeking a declaration that the manufacture and sale of generic donepezil covered by its second ANDA would not infringe the claims of the DJ patents. App. 7a. Teva initially alleged that it faced a restraint on its ability to market generic donepezil because of the potential risk of future suit on the two non-disclaimed DJ patents (the '911 and '760 patents). With respect to the patents that Eisai had already disclaimed (the '864 and '321 patents), Teva asserted that it

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nevertheless faced an injury because, as long as these patents remained listed in the Orange Book, Teva was unable to obtain final FDA approval of its second ANDA.

Eisai confirmed its prior disclaimer of the '864 and '321 patents, and then granted Teva a covenant-not-to-sue with respect to the '911 and '760 patents. Pursuant to the covenant, Eisai unconditionally confirmed that it would not assert the '911 and '760 patents against Teva with respect to any formulation of generic donepezil described in either of Teva's ANDAs. App. 8a.

Teva then filed an Amended Complaint withdrawing its allegations of harm based on a risk of future suit, and alleged solely an injury stemming from Teva's inability to secure immediate final FDA approval of its second ANDA. Teva's theory was that, in the absence of a declaratory judgment, it would need to wait 181 days after Ranbaxy began commercially marketing generic donepezil. Teva sought a declaratory judgment for the sole purpose of submitting that judgment to the FDA in order to trigger Ranbaxy's 180-day exclusivity period at a time when, due to the '841 patent, no party could market generic donepezil in any event. App. 8a. Eisai moved to dismiss for lack of subject matter jurisdiction.

### **3. Proceedings in the District Court**

The district court granted Eisai's motion to dismiss. The court observed that Eisai had no legal right to enforce the two disclaimed DJ patents (the '864 and '321 patents) against Teva and had given Teva a covenant-not-to-sue with respect to the

remaining two DJ patents (the '911 and '760 patents). App. 37a. Teva, therefore, faced no restraint on its ability to market generic donepezil due to a possibility that Eisai may bring an infringement suit on the DJ patents, a fact that Teva did not dispute. App. 37a-38a.

The court then addressed Teva's contention that its inability to obtain immediate FDA approval while the DJ patents remained listed in the Orange Book constituted an injury of sufficient immediacy and reality to justify declaratory judgment jurisdiction for a patent infringement action. App. 39a. The district court examined the Federal Circuit's two main pronouncements on subject matter jurisdiction having opposing outcomes in the context of the Hatch-Waxman Act: *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), and *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1631 (2009). App. 39a-43a.

In *Caraco*, the Federal Circuit found subject matter jurisdiction where a favorable declaratory judgment with respect to a later-expiring patent would have triggered (upon a successful conclusion of a separate infringement lawsuit with respect to the earlier-expiring listed patent for the same drug) the first ANDA filer's exclusivity period. App. 41a (citing *Caraco*, 527 F.3d at 1293). By contrast, in *Janssen* the Federal Circuit refused to find jurisdiction where the subsequent ANDA filer, in addition to facing the same limitations as the subsequent filer in *Caraco*, had stipulated to the validity, infringement, and enforceability of a separate earlier-expiring active

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ingredient patent. App. 43a (citing *Janssen*, 540 F.3d at 1361).

The district court concluded that this case was analogous to *Janssen* and rejected Teva's injury claim as not presenting an adequate controversy under the Declaratory Judgment Act. Irrespective of the DJ patents and Ranbaxy's exclusivity period, Teva was under no threat of patent infringement from the DJ patents and was prevented from marketing its generic donepezil product by the preliminary injunction imposed with respect to any product covered by the '841 patent. App. 45a. This injunction in any event "deprive[d] any hypothetical FDA-approval-blocking injury [claimed by Teva] of the requisite immediacy and reality to warrant declaratory judgment jurisdiction." *Id.*

Refusing to "speculate ... as to whether the preliminary injunction will be lifted and whether Teva may market any form of generic donepezil prior to the expiration of the '841 patent," the district court held that "the potential injury alleged by Teva ... lack[ed] the sufficient immediacy and reality to establish declaratory judgment jurisdiction." App. 46a. The district court also concluded that, in the alternative, it would exercise its discretion under the Declaratory Judgment Act to decline jurisdiction. App. 47a.

#### **4. Proceedings in the Federal Circuit**

##### **a. Judgment**

On appeal, the Federal Circuit reversed the district court's judgment of dismissal, finding subject matter jurisdiction for a declaratory judgment patent

infringement action involving, among other things, patents disclaimed before the action had even been filed.

The Federal Circuit reaffirmed its prior holding in *Caraco* that a judicially cognizable injury-in-fact occurs “when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs.” App. 11a. Under the rule set forth in *Caraco*, the action that gave rise to the requisite injury-in-fact was the pioneer drug company’s “listing [of] particular patents in the Orange Book,” which had occurred several years before Teva’s ANDA even existed. *Id.* (citing *Caraco*, 527 F.3d at 1292; *Janssen*, 540 F.3d at 1359-60). The Federal Circuit reasoned that this “injury (i.e., exclusion from the market) is fairly traceable to the defendant’s [the pioneer drug company’s] actions because ‘but-for’ the defendant’s decision to list a patent in the Orange Book, FDA approval of the generic drug company’s ANDA would not have been independently delayed by that patent.” *Id.* (citations omitted). In the court of appeals’ view, the Orange Book listing is an “independent barrier” to Teva entering the marketplace, and this independent barrier “cannot be overcome without a court judgment that the listed patent is invalid or not infringed.” *Id.* The Federal Circuit then concluded that the “the company manufacturing the generic drug has been deprived of an economic opportunity to compete,” and therefore suffered an injury-in-fact. *Id.* (citations omitted).

Applying *Caraco*, the Federal Circuit below held that Teva’s declaratory action presented an actual controversy. App. 13a. In the court’s view, a judgment favorable to Teva on the DJ patents “would

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eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.” *Id.* (quoting *Caraco*, 527 F.3d at 1293). The Federal Circuit expressly rejected the argument that Eisai’s statutory disclaimers and covenant-not-to-sue rendered Teva’s declaratory action moot. The court of appeals opined that Eisai’s inability to bring an infringement action with respect to the DJ patents was irrelevant, because “the DJ patents remain[ed] listed in the Orange Book,” and so Teva “still need[ed] a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market.” App. 13a n.3.

The parties’ July 2010 stipulation, approved by the district court, to discontinue any litigation over the ’841 patent and to maintain the preliminary injunction in effect until that patent’s expiration did not alter the Federal Circuit’s conclusion. App. 14a n.4. The Federal Circuit also concluded that the district court abused its discretion in declining jurisdiction under the Declaratory Judgment Act. App. 15a-17a.

**b. Denial of Rehearing and  
Motion for Vacatur on the  
Grounds of Mootness**

On November 4, 2010, Eisai filed a petition for rehearing and rehearing *en banc*. While the rehearing petition was pending, and after the ’841 patent expired on November 25, 2010, Ranbaxy commenced commercial sales of its generic donepezil product in the United States on November 30, 2010. *See* Ranbaxy Launches Donepezil 5 mg and 10 mg Tablets to U.S. Healthcare System/Ranbaxy Granted 180-Day Sole Marketing Exclusivity (Nov. 30, 2010),

<http://www.ranbaxy.com/news/newsdisp.aspx?cp=968&flag=LN>.

Ranbaxy's commercial launch triggered its 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv). As a result, Teva would be able to receive final FDA approval and enter the market 181 days thereafter, irrespective of its declaratory judgment action. The triggering of Ranbaxy's 180-day exclusivity was the only relief that Teva sought to obtain through its declaratory judgment action. Ranbaxy's launch also confirmed the error of the Federal Circuit's reasoning that Teva's inability to enter the market (created by Ranbaxy's status as the first-filing generic drug applicant) could be addressed only *via* a declaratory judgment of patent noninfringement against Eisai.

On December 3, 2010, Eisai submitted a letter to the Federal Circuit informing it of Ranbaxy's launch and requesting vacatur of the panel opinion in accordance with its then-pending petition. On the same day, Teva filed a suggestion of mootness. Teva characterized Ranbaxy's launch as an "intervening action by a third party" and stated that "[s]ince Teva's declaratory judgment action was predicated on the need for a judgment to trigger Ranbaxy's exclusivity, that claim is now moot." Suggestion of Mootness on Behalf of Plaintiff-Appellant Teva Pharmaceuticals USA, Inc., No. 09-1593, at 3 (Fed. Cir. Dec. 3, 2010).

On December 6, 2010, the clerk docketed both Eisai's notice letter and Teva's suggestion of mootness and the docket reflects that both were sent to the panel. On the same day, the Federal Circuit

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denied the petition for rehearing and rehearing *en banc*. App. 52a-53a.

On December 7, 2010, Eisai formally moved to vacate the Federal Circuit's judgment. Eisai noted that the parties agreed that the controversy was moot, and argued that "[w]here, as here, mootness is not the result of a deliberate action by a party, the proper remedy is vacatur of the court decisions in the action, including a decision by the Court of Appeals." Defendants-Appellees' Motion for Stay of Mandate and Vacatur for Mootness, No. 09-1593, at 4-5 (Fed. Cir. Dec. 7, 2010) (citing *Arizonans for Official English v. Ariz.*, 520 U.S. 43, 71-73 (1997)). Teva opposed the motion. It did not claim that Eisai had taken any action that rendered vacatur inequitable. Rather, Teva relied on authority from other circuits to argue that, in the absence of "public policy concerns," vacatur should be denied when all that remained is "the 'ministerial act of issuing the mandate.'" Opposition of Plaintiff-Appellant Teva Pharmaceuticals USA, Inc. to Defendants-Appellees' Motion of Stay of Mandate and Vacatur for Mootness, No. 09-1593, at 1-2 (Fed. Cir. Dec. 9, 2010) (quoting *Humphreys v. Drug Enforcement Admin.*, 105 F.3d 112, 115 (3d Cir. 1996)).

The Court denied Eisai's vacatur motion on December 10, 2010 — the same day Eisai filed its reply in support of that motion, see Defendants-Appellees' Reply in Support of Motion for Stay of Mandate and Vacatur for Mootness, No. 09-1593 (Fed. Cir. Dec. 10, 2010) — and on December 13, 2010 issued its unaltered mandate to the district court finding subject matter jurisdiction and remanding for

proceedings consistent with its opinion of jurisdiction. App. 18a-21a.

In the district court, Teva moved to dismiss its complaint on December 20, 2010, and the district court terminated the action the next day. App. 51a.

**REASONS FOR GRANTING THE PETITION  
AND VACATING THE JUDGMENT BELOW**

**A. Vacatur Is the Proper Remedy When  
Mootness Occurs Through Happenstance  
and Not Any Voluntary Act of a Party.**

In *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), this Court stated that “[t]he established practice of the Court in dealing with a civil case from a court in the federal system which has become moot *while on its way here or pending our decision on the merits* is to reverse or vacate the judgment below and remand with a direction to dismiss.” *Id.* at 39 (emphasis added). Vacatur “clears the path for future relitigation of the issues between the parties and eliminates a judgment, review of which was prevented through happenstance.” *Id.* at 40.

In *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994), this Court clarified that “[t]he reference to ‘happenstance’ in *Munsingwear* must be understood as an allusion to this equitable tradition of vacatur. A party who seeks review of the merits of an adverse ruling, but is frustrated by the vagaries of circumstance, ought not in fairness be forced to acquiesce in the judgment.” *Id.* at 25. By contrast, vacatur is generally not proper when a party has settled a case while an appeal is pending, and thus “has voluntarily forfeited his legal

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remedy by the ordinary processes of appeal or *certiorari*,” rather than being deprived of it. *Id.* at 25 (emphasis added). In that circumstance, “[t]he denial of vacatur is merely one application of the principle that ‘[a] suitor’s conduct in relation to the matter at hand may disentitle him to the relief he seeks.’” *Id.* (quoting *Sanders v. United States*, 373 U.S. 1, 17 (1963)) (additional citation omitted). With that exception, this Court followed *Munsingwear* in holding that “mootness by happenstance provides sufficient reason to vacate.” *Id.* at 25 & n.3. Noting that vacatur is an equitable remedy that accounts for the public interest, this Court held that “the public interest is best served by granting relief when the demands of ‘orderly procedure,’ [*Munsingwear*,] 340 U.S., at 41, cannot be honored.” *U.S. Bancorp*, 513 U.S. at 27. *See also United States v. Hamburg-Amerikanische Packetfahrt-Actien Gesellschaft*, 239 U.S. 466, 477-78 (1916) (vacating as moot a court of appeals decision, because “the ends of justice exact that the judgment below should not be permitted to stand when, without any fault of the government, there is no power to review it upon the merits”); *S. Spring Hill Gold Mining Co. v. Amador Medean Gold Mining Co.*, 145 U.S. 300, 301-02 (1892) (reversing judgment below after Article III jurisdiction was lost subsequent to the decision in the circuit court).

This Court emphasized the same point in *Arizonans for Official English v. Arizona*, 520 U.S. 43 (1997):

Vacatur clears the path for future relitigation by eliminating a judgment the loser was stopped from opposing *on direct review*. Vacatur is in order when

mootness occurs through happenstance — circumstances not attributable to the parties — or, relevant here, the unilateral action of the party who prevailed in the lower court.

*Id.* at 71-72 (internal quotation marks and citations omitted) (emphasis added).

The Federal Circuit’s denial of vacatur is flatly contrary to *Munsingwear* and *U.S. Bancorp*, and cannot be justified by the mere fact that the mooting event occurred after its judgment had been issued (but before it became final). This Court routinely vacates appellate court judgments that subsequently become moot. In *Alvarez v. Smith*, 130 S. Ct. 576 (2009), this Court followed its “ordinary practice” of vacating appellate judgments that became moot while on certiorari review, noting that “there is not present here the kind of ‘voluntary forfeiture’ of a legal remedy that led the Court in *Bancorp* to find that considerations of ‘fairness’ and ‘equity’ tilted against vacatur.” *Id.* at 583; *see also Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) (vacating as moot a court of appeals judgment that became moot while on certiorari review); *Stewart v. S. Ry. Co.*, 315 U.S. 784 (1942) (vacating the judgment that became moot on petition for rehearing after case was decided on the merits, 315 U.S. 283 (1942)). Indeed, to avoid the unnecessary burden of forcing petitioners to seek the intervention of this Court, the Wright & Miller treatise declares that, “[g]iven the Supreme Court practice, it is appropriate for a court of appeals to vacate its own judgment if it is made aware of events that moot the case during the time available to seek certiorari.” 13C Charles Alan Wright et al., *Federal*

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*Practice and Procedure* § 3533.10.3, at 628 (3d ed. 2008) (hereinafter Wright et al., *Federal Practice and Procedure*).

Finally, the Federal Circuit's refusal to vacate its judgment draws it into conflict with *Great Western Sugar Co. v. Nelson*, 442 U.S. 92 (1979) (per curiam), and *Duke Power Co. v. Greenwood County*, 299 U.S. 259, 267 (1936). Those precedents establish the rule that "[w]here it appears upon appeal that the controversy has become entirely moot, it is the duty of the appellate court to set aside the decree below and to remand the cause with directions to dismiss." *Great W.*, 442 U.S. at 93 (quoting *Duke Power*, 299 U.S. at 267) (emphasis added). Here, because the Federal Circuit refused to vacate or amend its judgment to reflect mootness, the mandate issued finding subject matter jurisdiction and remanding the case to the district court to proceed on the merits. App. 18a-19a. The district court properly dismissed the case notwithstanding this erroneous mandate, but only when Teva voluntarily withdrew its declaratory-judgment complaint. The district court's dismissal does not rectify the Federal Circuit's failure in its duty to vacate both its own judgment and the one below on mootness grounds. Nor does the district court have the power to vacate the Federal Circuit's decision.

It is this Court's established practice to vacate summarily decisions of the court of appeals that have become moot after the judgment of the court of appeals. 13C Wright et al., *Federal Practice and*

*Procedure* § 3533.10.3, at 626-28.<sup>4</sup> Although the Federal Circuit should have done so before issuance of its mandate and thereby obviated the need for this Court's intervention, the Court should grant its customary relief here.

**B. An Acknowledged and Deep Conflict in the Courts of Appeals Warrants Review.**

If for any reason this Court were not to follow its established vacatur practice, it should set for argument the question of whether a court of appeals that still has jurisdiction may disregard the *Munsingwear* vacatur rule simply because the court of appeals has already issued its judgment. This Court's review is necessary to resolve an acknowledged conflict in the courts of appeals.

The Fifth, Eleventh, and D.C. Circuits follow the rule that the *Munsingwear* vacatur is proper even after an appellate judgment has been issued but prior to the issuance of the mandate, and the Eighth Circuit has gone even farther to recall a mandate to vacate its judgment that subsequently became moot.

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<sup>4</sup> See, e.g., *Hollingsworth v. United States Dist. Court*, 131 S. Ct. 372 (2010) (vacating Ninth Circuit judgment denying the petition for mandamus after it subsequently became moot); see also *Ind. State Police Pension Trust v. Chrysler LLC*, 130 S. Ct. 1015 (2009); *al-Marri v. Spagone*, 129 S. Ct. 1545 (2009); *Radian Guar., Inc. v. Whitfield*, 553 U.S. 1091 (2008); *Selig v. Pediatric Specialty Care, Inc.*, 551 U.S. 1142 (2007); *Harper v. Poway Unified Sch. Dist.*, 549 U.S. 1262 (2007); 13C Wright et al., *Federal Practice and Procedure* § 3533.10.3, at 626 n.6 (citing additional cases).

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In *United States v. Caraway*, 483 F.2d 215 (5th Cir. 1973) (en banc) (per curiam), the case became moot after the court of appeals issued its judgment on the merits when the district court dismissed the indictment while the appeal was still pending. Citing *Munsingwear*, the Fifth Circuit held that “[t]he judgments of conviction giving rise to the appeal as well as the panel opinion of this court, are vacated. The indictment having been dismissed, it will be necessary to remand to the district court only for the purpose of setting aside the judgments of conviction on the ground of mootness.” *Id.* at 216 (citing *Munsingwear*, 340 U.S. at 39-40) (additional citations omitted). See also *United States v. Miller*, 685 F.2d 123, 124 (5th Cir. 1982) (per curiam) (vacating its opinion on learning “[b]efore issuance of the mandate” that the case had become moot).

The D.C. Circuit has likewise vacated as moot a judgment in which the mooting event occurred after judgment but during the pendency of a petition for rehearing, citing this Court’s decisions in *Munsingwear* and *Stewart*. See *Clarke v. United States*, 915 F.2d 699, 706 (D.C. Cir. 1990) (en banc). The Court also noted that, even if vacatur was discretionary and not automatic, it would reach the same result. *Id.* at 708. The D.C. Circuit later reiterated the *Clarke* rule, establishing an exception for settlement that this Court subsequently recognized in *U.S. Bancorp. In re United States*, 927 F.2d 626, 627 (D.C. Cir. 1991); see also *United States v. Schaffer*, 240 F.3d 35, 38 (D.C. Cir. 2001) (en banc) (per curiam) (reiterating its general rule — except for instances of settlement or a party’s voluntary act — of vacating “any outstanding panel decisions” when “a case becomes moot on appeal, whether it be during

initial review or in connection with consideration of a petition for rehearing or rehearing *en banc*").

Similarly, the Eleventh Circuit vacated a judgment that became moot after judgment but within the time for filing of a petition for rehearing *en banc*. The court of appeals declared that "[w]e see no reason why this court should not declare the case moot when the mandate has not yet issued, if the Supreme Court can do the same while the case is pending before it on petition for certiorari, that is, the Court has not yet taken jurisdiction." *In re Ghandtchi*, 705 F.2d 1315, 1316 (11th Cir. 1983) (per curiam); see also *Nat'l Solid Wastes Mgmt. Ass'n v. Ala. Dep't of Env'tl. Mgmt.*, 924 F.2d 1001, 1002 n.1 (11th Cir. 1991) (per curiam) (reaffirming *In re Ghandtchi*); *Key Enters. v. Venice Hosp.*, 9 F.3d 893, 898-99 & n.10 (11th Cir. 1993) (en banc) (per curiam) (same).

The Eighth Circuit has gone even further, recalling a mandate to vacate a judgment in a case that subsequently became moot. The court declared that the "case became moot after the mandate issued, but during the time available to seek certiorari, when appellant was released from custody on February 19, 1988." *Brewer v. Swinson*, 837 F.2d 802, 806 (8th Cir. 1988). The Eighth Circuit accordingly "vacate[d] the judgment of the court of appeals," vacated the district court judgment, and remanded the case to the district court with directions to dismiss the case as moot. *Id.*

By contrast, the Second, Third, Ninth, and Tenth Circuits (and now the Federal Circuit) follow the rule that a court of appeals has greater discretion to deny vacatur after it has issued its judgment (even in the absence of inequitable actions by the parties), and the

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Ninth Circuit has expressly acknowledged its rejection of the Fifth Circuit's *Caraway* rule. *United States v. Payton*, 593 F.3d 881, 884 n.2 (9th Cir. 2010). As one court summarized the rationale of the appellate-judgment rule adopted by these circuits:

“Because the obligations of the parties are not fixed until the Court's mandate issues, it would appear to follow that the Court retains authority to amend its judgment until it issues its mandate. Nonetheless, the extent of a Court's supervision of a case between entry of judgment and issuance of mandate should not be overstated. Issuance of mandate is largely a ministerial function, and follows automatically ... after entry of judgment, unless stayed. For most purposes, the entry of judgment, rather than the issuance of mandate, marks the effective end to a controversy on appeal.”

*Bastien v. Office of Senator Ben Nighthorse Campbell*, 409 F.3d 1234, 1235 (10th Cir. 2005) (per curiam) (emphasis omitted) (quoting *Finberg v. Sullivan*, 658 F.2d 93, 97 n.5 (3d Cir. 1980) (en banc)). Thus, in these circuits, the fact that the court of appeals had already issued its judgment weighs against vacatur:

“[T]his case is not one that became moot while ‘on its way here’ or while ‘pending our decision on the merits.’ Rather, we heard and determined the merits of the appeal. As of the time our decision was filed, there was indisputably a live controversy between the parties ....”

*Id.* (quoting *Humphreys*, 105 F. 3d at 115); *see also Armster v. United States Dist. Court*, 806 F.2d 1347, 1355 (9th Cir. 1986) (“There is a significant difference between a request to dismiss a case or proceeding for mootness prior to the time an appellate court has rendered its decision on the merits and a request made after that time ...”); *In re Grand Jury Investigation*, 399 F.3d 527, 529 n.1 (2d Cir. 2005) (“We generally have discretion, moreover, to leave our order intact where the circumstances leading to mootness occur after we file our decision but before the mandate has issued.”); *Mfrs. Hanover Trust Co. v. Yanakas*, 11 F.3d 381, 384 (2d Cir. 1993) (denying vacatur of the court of appeals’ judgment where “the appeal has already been decided” and only discretionary review by way of petition for rehearing or for certiorari was available). This Court should resolve an acknowledged conflict of this magnitude on an important and recurring issue.

**C. The Issuance of a Judgment by a Court of Appeal Does Not Affect the *Munsingwear* Analysis.**

Not only should the conflict among the circuits be resolved, but the appellate-judgment rule followed by the latter group of courts is flatly inconsistent with this Court’s *Munsingwear* precedents. A court of appeals is an intermediate court in the Article III hierarchy. Article III creates

not a batch of unconnected courts, but a judicial *department* composed of “inferior Courts” and “one supreme Court.” Within that hierarchy, the decision of an inferior court is not (unless the time for

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appeal has expired) the final word of the department as a whole.

*Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 227 (1995). That is why this Court has emphasized that “[t]he established practice of the Court in dealing with a civil case from a court in the federal system which has become moot *while on its way here or pending our decision* on the merits is to reverse or vacate the judgment below and remand with a direction to dismiss.” *Munsingwear*, 340 U.S. at 39 (emphasis added); *U.S. Bancorp*, 513 U.S. at 25 (vacatur rule depends on whether the affected party “has voluntarily forfeited his legal remedy by the ordinary processes of appeal or certiorari”). The courts of appeals following the appellate-judgment rule erroneously take the contrary view that the relevant consideration is whether mootness occurs prior to *their* final judgment, as opposed to the *judicial department’s* final judgment. See *Humphreys*, 105 F. 3d at 115 (justifying the appellate-judgment rule because after a *court of appeals* renders judgment, “th[e] case is not one that became moot while ‘on its way here’ or while ‘pending our decision on the merits.’”). But this Court has clearly declared that the purpose of vacatur is to “clear[] the path for future relitigation by eliminating a judgment the loser was stopped from opposing *on direct review*.” *Arizonans*, 520 U.S. at 71 (emphasis added) (internal quotation marks omitted). Indeed, if the issuance of a court of appeals judgment had any equitable relevance, then there would be no basis for this Court’s practice of summarily vacating cases that become moot. See *Alvarez*, 130 S. Ct. at 583, and cases cited *supra* at 24 n.4.

Nothing in the equitable or discretionary nature of vacatur supports the appellate-judgment rule. Judicial discretion is constrained by the “equitable tradition of vacatur,” which recognizes that “[a] party who seeks review of the merits of an adverse ruling, but is frustrated by the vagaries of circumstance, ought not in fairness be forced to acquiesce in the judgment.” *U.S. Bancorp*, 513 U.S. at 25. This equitable rule accounts for the public interest: “*Munsingwear* establishes that the public interest is best served by granting relief when the demands of ‘orderly procedure,’ 340 U.S. at 41, cannot be honored.” *U.S. Bancorp*, 513 U.S. at 27. To be sure, vacatur may be denied when the actions of the party in causing mootness shift the equities against it, as when the party settles the case, thereby “voluntarily forfeit[ing] his legal remedy by the ordinary processes of appeal or certiorari.” *Id.* at 25. And a court always has discretion to take into account “exceptional circumstances.” *Id.* at 29. But in the absence of such exceptional circumstances, the Court has no discretion to disregard the *Munsingwear* rule simply because a court of appeals desires to maintain its own judgment.

Because this case became moot solely by the happenstance of Ranbaxy’s commercial launch, under *Munsingwear* Eisai should not be forced to acquiesce in the Federal Circuit’s erroneous judgment that a district court has Article III jurisdiction to issue a declaratory judgment on infringement even when the defendant has disclaimed the patent or given a covenant-not-to-sue. Jurisdictional holdings in an unvacated judgment are given preclusive effect. See *Am. Sur. Co. v. Baldwin*, 287 U.S. 156, 166 (1932) (“The principles of *res judicata* apply to questions of

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jurisdiction as well as to other issues.”); *Baldwin v. Iowa State Traveling Men’s Ass’n*, 283 U.S. 522, 524-26 (1931); *Stewart Sec. Corp. v. Guar. Trust Co.*, 597 F.2d 240, 242-43 (10th Cir. 1979). It is simply inequitable for the judgment below not to be vacated when happenstance deprived Eisai of the opportunity to seek review and reversal in this case.

There was a reasonable likelihood that this Court would have granted certiorari to review the underlying judgment had it not become moot. The existence of an Article III controversy is determined on a claim-by-claim basis. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 351-53 (2006). Thus, there must be adversity between the parties on each of Teva’s declaratory judgment claims that its generic products do not infringe the four DJ patents. But there is no such adversity as to disclaimed patents, or ones where there is a covenant-not-to-sue. A disclaimer withdraws statutory protection from the claims and extinguishes them *ab initio*; the patentee no longer has any property right in the patent. *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935); *Underwood v. Gerber*, 149 U.S. 224, 231 (1893); *Guinn*, 96 F.3d at 1422. Unlike the patents at issue in *MedImmune*, 549 U.S. 118, both the disclaimed and covenanted patents were simply not enforceable against Teva.<sup>5</sup>

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<sup>5</sup> *MedImmune* did not dispense with the requirement of party adversity with regard to a claim of infringement or invalidity: *i.e.*, the requirement that the defendant must have patent rights enforceable against the declaratory-judgment plaintiff. In *MedImmune*, the respondent patentee had issued “a threat by respondents to enjoin sales if royalties [were] not forthcoming” under a license agreement. 549 U.S. at 128. The licensee  
(continued...)

In the Federal Circuit's unprecedented conception of Article III jurisdiction, district courts must construe legally non-existent or unassertable patent claims and determine whether the generic competitor's products would have infringed the claims (had they still existed). The Federal Circuit improperly eliminated the Article III requirement of adversity between the parties with regard to the legal claim to be adjudicated. Instead, the court of appeals focused on the questions of what benefits under the Hatch-Waxman Act against a non-party would accrue to Teva by obtaining a declaratory patent judgment against Eisai — questions that are not germane to

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(...continued)

staved off an infringement suit by continuing to pay royalties even as it challenged the patent's validity. This Court rejected the Federal Circuit's earlier rule that there is no Article III controversy unless the declaratory judgment plaintiff demonstrates a "reasonable apprehension" of suit. 549 U.S. at 122 (internal quotation marks and citation omitted). The Court explained that "the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity," and so a plaintiff is not required to take the potentially illegal action and risk "treble damages and the loss of 80 percent of its business" before seeking declaratory judgment. *MedImmune*, 549 U.S. at 129, 134 (quoting *Steffel v. Thompson*, 415 U.S. 452, 480 (1974) (Rehnquist, J., concurring)). Nothing in *MedImmune* authorizes a declaratory action for patent infringement where the patents were nullities in the eyes of the law or otherwise were unenforceable against the patentee.

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the patent subject matter jurisdiction inquiry. App. 11a-14a & n.4.<sup>6</sup>

Mootness deprives this Court of the ability to review the decision below for its correctness, but not the power to vacate it. *U.S. Bancorp*, 513 U.S. at 21-22. In vindication of its *Munsingwear* doctrine and the equitable rights of petitioner not to be bound by a judgment when review is foreclosed by happenstance, this Court should vacate the judgment of the Court of Appeals summarily, or in the alternative grant the petition and set the case for oral argument to resolve the conflict in the circuits.

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<sup>6</sup> Although the petition for certiorari that Eisai would have filed would have been strong, the Court does not take that into account in its vacatur decisions. See *U.S. Bancorp*, 513 U.S. at 27 (vacatur in cases “in which we have no constitutional power to decide the merits” should not depend on “assumptions about the merits”), *id.* at 28 (“We again assert the inappropriateness of disposing of cases, whose merits are beyond judicial power to consider, on the basis of judicial estimates regarding their merits.”). As noted above, this Court simply vacates inferior court judgments that become moot while subject to review by this Court.

## CONCLUSION

The petition for a writ of certiorari should be granted, and the judgment of the court of appeals vacated for mootness.

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