No. 10-____

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,[1] 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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[1] 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).

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

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

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).[2]

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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[2] 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).[3] 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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[3] 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

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

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

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

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

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

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*

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.[4] 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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[4] *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).

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 Envtl. 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

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

> 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

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.[5]

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[5] *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.

the patent subject matter jurisdiction inquiry. App. 11a-14a & n.4.[6]

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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[6] 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.

Respectfully submitted,

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February 2011

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2009-1593

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff-Appellant,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants-Appellees.

Appeal from the United States District Court for the District of New Jersey in case no. 08-CV-2344, Chief Judge Garrett E. Brown, Jr.

Decided: October 6, 2010

Francis C. Lynch, Goodwin Proctor LLP, of Boston, MA, argued for plaintiff-appellant. With him on the brief were Henry C. Dinger and Laurie S. Gill.

Bruce M. Wexler, Paul, Hastings, Janofsky & Walker LLP, of New York, NY, argued for defendants-appellees. With him on the brief were Joseph M. O'Malley, Jr. and Anthony Michael; and Stephen B. Kinnaird, of Washington, DC.

Before RADER, Chief Judge[*], DYK and PROST, Circuit Judges.

PROST, Circuit Judge.

This is a declaratory judgment action arising under the Hatch-Waxman Act. We must decide whether the district court properly dismissed the case for lack of jurisdiction, specifically, lack of a justiciable controversy under Article III of the United States Constitution.

Teva Pharmaceuticals, Inc. ("Teva") seeks to manufacture and market a generic version of the drug donepezil hydrochloride ("donepezil"), an approved treatment for Alzheimer's disease. Eisai Co. and Eisai Medical Research, Inc. (collectively "Eisai") hold the approved New Drug Application ("NDA") for donepezil, which Eisai currently markets as Aricept®. Eisai also owns the five patents listed for Aricept® in the Orange Book. Teva requests a declaratory judgment that its generic version of donepezil does not infringe four of these Orange Book patents, 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").

Aside from the value of such a judgment in itself, a finding of noninfringement has special significance to generic drug manufacturers like Teva under the Hatch-Waxman Act. To market a generic version of a previously-approved drug, manufacturers must file and receive approval of an Abbreviated New Drug Application ("ANDA"). In conjunction with an ANDA, manufacturers must also submit a certification with

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[*] Randall R. Rader assumed the position of Chief Judge on June 1, 2010.

respect to each of the drug's Orange Book patents. The first manufacturer to file what is called a "Paragraph IV Certification" for a given Orange Book patent is entitled to 180 days of generic marketing exclusivity. Until the first-filer's exclusivity period has run, the FDA may not approve ANDA applications by other manufacturers who have filed Paragraph IV certifications for that same patent. The first-filer's exclusivity period can be triggered by either the (1) commercial marketing of the drug by the first Paragraph IV filer or (2) entry of a court judgment finding that patent invalid or not infringed, whichever happens first. A subsequent Paragraph IV filer can thus trigger the first-filer's exclusivity period by obtaining a court judgment.

Teva is a subsequent Paragraph IV filer. This case turns on whether a subsequent Paragraph IV filer has a legally cognizable interest in when the first-filer's exclusivity period begins, such that delay in triggering that period qualifies as "injury-in-fact" for the purposes of Article III.

In this case, the alleged injury-in-fact stems from a pending ANDA filed by Gate Pharmaceuticals ("Gate ANDA" or "second ANDA"), an unincorporated division of Teva. FDA approval of the Gate ANDA has been delayed indefinitely because the exclusivity period of the first-filer, a company called Ranbaxy Laboratories Ltd. ("Ranbaxy"), has not been triggered. Before the district court, patent owner Eisai argued that Teva failed to establish the existence of an Article III controversy. The district court agreed and dismissed the case for lack of jurisdiction. In finding that Teva failed to allege a controversy of sufficient immediacy and reality for Article III purposes, the

district court relied in part on a preliminary injunction entered against Teva and Gate in a separate, still-pending patent infringement action regarding Patent No. 4,895,841 ("'841 patent").[1]

Teva appeals the dismissal of its declaratory judgment action and argues the case should proceed. We agree. Under this court's decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed.Cir.2008), Teva has alleged a sufficiently concrete injury fairly traceable to Eisai's actions. Further, the injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger the first-filer's exclusivity period, which currently blocks FDA approval of the Gate ANDA. The district court's decision is reversed and the case remanded for further proceedings consistent with this opinion.

BACKGROUND

Because Teva's declaratory judgment claims were disposed of at the motion to dismiss stage, we take the following facts from Teva's amended complaint and the materials submitted in response to Eisai's motion to dismiss. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 121 (2007).

Eisai holds the approved New Drug Application ("NDA") for donepezil, which it markets as the prescription drug Aricept®. For Aricept®, Eisai listed five patents in the Orange Book, thus attesting that those patents claim either donepezil or a method for using it, and accordingly could reasonably be asserted

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[1] The '841 patent is listed in the Orange Book for Aricept®. It is not, however, one of the patents as to which Teva seeks a declaratory judgment of noninfringement in this case.

against any unlicensed party seeking to manufacture, use, or sell the drug. Of the five patents, the '841 patent is the subject of separate patent infringement litigation brought by Eisai against Teva and Gate. The four DJ patents are at issue here.

A significant number of events occurred before Teva brought this action. While the timeline and statutory scheme is complex, for our purposes, only the following facts matter.

The first ANDA for a generic form of donepezil was filed by Ranbaxy in 2003. For the '841 patent, Ranbaxy submitted a Paragraph III certification, thus agreeing not to market a generic version of Aricept® until after the '841 patent expires in November 2010. For the DJ patents, Ranbaxy submitted Paragraph IV certifications, meaning that in Ranbaxy's opinion the four patents are invalid or will not be infringed by its drug. 21 U.S.C. § 355(j)(2)(A)(vii). Because Ranbaxy filed the first Paragraph IV certifications for the DJ patents, Ranbaxy is eligible for 180 days of market exclusivity upon FDA approval of its ANDA. *Id.* § 355(j)(5)(B)(iv). The exclusivity period begins when Ranbaxy begins commercially marketing its drug or upon issuance of a court judgment holding the relevant listed patents invalid or not infringed. *Id.* § 355(j)(5)(B)(iv) (2000).[2]

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[2] In 2003, Congress altered the scheme for triggering the 180-day exclusivity period by amending the Hatch-Waxman Act. As a result, a first-filer can now forfeit its exclusivity period by failing to market its drug within a certain time. *See* 21 U.S.C. § 355(j)(5)(D). These changes do not apply here because Ranbaxy filed its ANDA with the Paragraph IV certifications before enactment of the amendments. *See* Medicare Prescription Drug,

(continued...)

Teva subsequently filed two separate ANDAs for generic donepezil. As initially filed with the FDA, Teva's first ANDA ("first ANDA" or "Teva ANDA") had the same certifications as Ranbaxy's ANDA: For the '841 patent, Teva initially included a Paragraph III certification; for the DJ patents, Teva included Paragraph IV certifications. Teva subsequently amended this first ANDA, changing the '841 patent's certification from Paragraph III to Paragraph IV.

Teva's second ANDA ("second ANDA" or "Gate ANDA") was filed by Gate Pharmaceuticals, a division of Teva. This second ANDA was for a different form of generic donepezil than the one claimed in Teva's first ANDA. According to Teva, the FDA requested separate ANDAs filed under different company names because the forms of donepezil were different and the likelihood of confusion otherwise greater. The Gate ANDA originally included Paragraph III certifications for all five listed patents; following an amendment, however, these were changed to Paragraph IV certifications.

Under the Hatch-Waxman Act, filing a Paragraph IV certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2). After Teva filed its first and second ANDAs in 2005 and 2007 respectively, Eisai timely sued Teva for infringement of the '841 patent ("'841 patent infringement litigation"). 21 U.S.C. § 355(c)(3)(C) (2000). Though filed separately, these two infringement actions were consolidated in early 2008. During the course of the

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(...continued)

Improvement, and Modernization Act of 2003, § 1102(b), Pub.L. No. 108-173, 117 Stat.2066 (2003).

litigation, Teva stipulated that its generic forms of donepezil infringe various claims of the '841 patent unless the patent is invalid or unenforceable.

In February 2008, Eisai moved for a preliminary injunction to prevent Teva and Gate from marketing any form of generic donepezil after expiration of the thirty-month stay invoked by Eisai, thereby initiating the '841 patent infringement litigation. *See id.* § 355(j)(5)(B)(iii). Eisai's motion was granted and a preliminary injunction entered against Teva and Gate. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 05-5727, 2008 WL 1722098 (D.N.J. Mar. 28, 2008) (opinion and order granting preliminary injunction). The preliminary injunction bars Teva and Gate from marketing any drug containing donepezil as claimed in the '841 patent. In April 2008, the thirty-month stay expired and the FDA approved Teva's first ANDA. At the time of this appeal, the separate '841 patent infringement litigation is still pending and the related preliminary injunction is still in effect.

In May 2008, Teva filed this action. Here, Teva seeks a declaratory judgment that the manufacture, use, offer for sale, sale, or importation of generic donepezil covered by the Gate ANDA will not infringe the DJ patents. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5). Eisai has never brought suit to enforce any of the DJ patents against Teva. Rather in 2006 and 2007, before this case arose, Eisai filed statutory disclaimers with the United States Patent and Trademark Office regarding two of the DJ patents, the '321 and '864 patents. *See* 35 U.S.C. § 253. A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently enforced. *See Guinn v. Kopf*, 96 F.3d

1419, 1422 (Fed.Cir.1996). What matters for our purposes is that all four of the DJ patents remain listed in the Orange Book.

Eisai moved to dismiss this case for lack of subject matter jurisdiction. While Eisai's motion was pending, the parties negotiated a covenant-not-to-sue covering the two DJ patents Eisai had not disclaimed, the '911 and '760 patents. Pursuant to the covenant, Eisai unconditionally agreed not to assert the '911 and '760 patents against Teva or its successors with respect to any formulation of generic donepezil described in Teva's first or second ANDAs. Before the district court and on appeal, Eisai relies in part on the statutory disclaimers and covenant-not-to-sue in arguing that there is no justiciable controversy.

Teva's amended complaint acknowledges the statutory disclaimers and covenant-not-to-sue. Teva nonetheless maintains that it is suffering an injury cognizable under Article III because the DJ patents remain listed in the Orange Book. Because the DJ patents remain listed, under 21 U.S.C. § 355(j)(5)(B)(iv) FDA approval of Teva's Gate ANDA cannot occur until the exclusivity period for the first-filer of the DJ patents, Ranbaxy, has run. As stated previously, the exclusivity period can only be triggered by the first-filer's commercial marketing of the generic drug or a court judgment that the relevant patents are invalid or not infringed. Given the framework of the Hatch-Waxman Act, Teva argues that the only way to redress its "FDA-approval-blocking-injury" is through this action for declaratory judgment.

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

ANALYSIS

We review a district court's dismissal for lack of subject matter jurisdiction de novo. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed.Cir.2008). Whether an actual controversy exists for purposes of a declaratory judgment action is a question of law also reviewed de novo. *Teva Pharms. USA v. Novartis Pharms. Corp.* ("*Novartis*"), 482 F.3d 1330, 1336 (Fed.Cir.2007). We review a district court's decision to decline jurisdiction under the Declaratory Judgment Act for abuse of discretion. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1287 (Fed.Cir.2007).

Under the Hatch-Waxman Act, a party that files an ANDA with Paragraph IV certifications may bring suit under the Declaratory Judgment Act, 28 U.S.C. § 2201, against the holder of the corresponding New Drug Application ("NDA"). 35 U.S.C. § 271(e)(5). The Declaratory Judgment Act provides that "[i]n the case of *actual controversy* within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). Federal courts have subject matter jurisdiction over cases brought by ANDA filers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Constitution requires an Article III case or controversy. *Novartis*, 482 F.3d at 1337.

The Supreme Court has explained that such a controversy exists when the dispute is "definite and concrete, touching the legal relations of parties having adverse legal interests." *MedImmune*, 549 U.S. at 128 (quoting *Aetna Life Ins. Co. v. Haworth*, 300

U.S. 227, 240-41 (1937)). This dispute must be "real and substantial," and of "sufficient immediacy and reality to warrant issuance of a declaratory judgment." *Id.* Further, the plaintiff's injury must be "fairly traceable" to the defendant's conduct. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998). Finally, the requested relief must be likely to redress the alleged injury. *Id.* In other words, the injury must "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune,* 549 U.S. at 128.

This case presents two questions. First, we must decide whether this case presents an "actual controversy." Should such a controversy exist, we must then decide if the district court abused its discretion under the Declaratory Judgment Act in declining to entertain this suit. We address each question in turn.

I. Actual Controversy

We begin with the jurisdictional question. Teva argues that absent a declaratory judgment with respect to the DJ patents, it suffers (and will continue to suffer) the harm of being unable to launch generic donepezil products covered by the Gate ANDA. Two decisions by this court set out the framework for determining whether an Article III controversy exists in a declaratory judgment action arising under the Hatch-Waxman Act, *Caraco* and *Janssen. See also* 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5); 28 U.S.C. § 2201.

Caraco holds that the exclusion of non-infringing generic drugs from the market can be a judicially

cognizable injury-in-fact. 527 F.3d at 1291-92. Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs. *See* 21 U.S.C. § 355(a); *Novartis,* 482 F.3d at 1345. In the cases of *Caraco* and *Janssen*, the alleged action taken (giving rise to the injury-in-fact) was listing particular patents in the Orange Book. *Caraco*, 527 F.3d at 1292; *Janssen*, 540 F.3d at 1359-60. As we explained in *Caraco,* the generic drug company's injury (i.e., exclusion from the market) is fairly traceable to the defendant'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. 527 F.3d at 1292; *see* 21 U.S.C. § 355(j)(5)(B)(iv). When an Orange Book listing creates an "independent barrier" to entering the marketplace that cannot be overcome without a court judgment that the listed patent is invalid or not infringed-as for Paragraph IV filers-the company manufacturing the generic drug has been deprived of an economic opportunity to compete. *Id.* at 1293; *see also* 21 U.S.C. § 355(j)(5)(B)(iv). A declaratory judgment redresses this alleged injury because it eliminates the potential for the corresponding listed patent to exclude the generic drug from the market. *Caraco*, 527 F.3d at 1293 (holding that a declaratory judgment action as to one of the listed patents would "clear the path to FDA approval that [the NDA holder's] actions would otherwise deny [the generic pharmaceutical]").

Though its facts were slightly different, *Janssen* reaffirms *Caraco's* holding that the injury-in-fact must stem from the actions of the company that listed the patents in the Orange Book, not the inherent framework of the Hatch-Waxman Act. *See Janssen*, 540 F.3d at 1360-61.

In *Janssen*, a subsequent Paragraph IV filer sought to trigger the first-filer's exclusivity period by obtaining a declaratory judgment. While the declaratory judgment action was pending, however, this subsequent filer stipulated to the validity, infringement, and enforceability of another patent listed in the Orange Book for the same drug. *Id.* As a result of the stipulation, even if the subsequent filer had prevailed in its declaratory judgment action, it could not have launched its generic drug before expiration of the patent covered by the stipulation. Accordingly, unlike in *Caraco*, there was no risk that invalid patents were keeping the subsequent filer's generic drugs off the market; regardless, the company could not have marketed its generic drug because of the stipulation. *Id.* at 1361. In other words, the subsequent filer's alleged harm, inability to enter the market, was not "fairly traceable" to the listing of the subject patents in the Orange Book. Rather, the cause was the stipulation. We further held in *Janssen* that the subsequent filer could not proceed with its declaratory judgment action simply to trigger the first-filer's exclusivity period. In contrast to the listing of a patent in the Orange Book, a first-filer's exclusivity period in itself does not give rise to an injury-in-fact because the resulting exclusion of other generic drug companies from the market results from the inherent framework and intended workings of the Hatch-Waxman Act. *Id.* at 1360-61.

We hold that this case presents an actual controversy. Here, as in *Caraco*, a favorable judgment "would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market." 527 F.3d at 1293. Unlike the generic drug company in *Janssen,* Teva has not stipulated to the validity, infringement, or enforceability of any other patent listed in the Orange Book for donepezil. 540 F.3d at 1360. Nor is Teva subject to any final judgment regarding an Orange Book patent for donepezil that would prevent Teva from selling products covered by the Gate ANDA. Given the absence of such factors, *Caraco* controls.[3] *See id.*

Eisai is correct that Teva and Gate have been subject to a preliminary injunction arising out of the separate '841 patent litigation, which barred Teva and Gate from marketing any drug containing donepezil as claimed in the '841 patent, including products covered by the Gate ANDA. As the name itself admits, however, that injunction was "preliminary." Indeed, the underlying litigation was still ongoing; there had been no final determination as to the validity, infringement, or enforceability of the '841 patent. Thus, unlike the generic drug company in *Janssen* which stipulated to the validity, enforceability and infringement of an Orange Book patent, there was no equivalent final judgment

[3] Neither the statutory disclaimers nor Eisai's covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book. *Caraco*, 527 F.3d at 1296-97. Thus, regardless of whether Eisai could bring an infringement action with respect to the DJ patents, under the Hatch-Waxman Act Teva still needs a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market. *Id.*

regarding the '841 patent. Indeed, Teva and Gate would not necessarily remain subject to an injunction, depending on the outcome of the '841 patent infringement litigation.[4]

II. Discretionary Dismissal

In the alternative, the district court stated that it would decline to entertain this suit pursuant to its broad discretion under the Declaratory Judgment Act. In support, the court cited the same reasons for finding no jurisdiction under Article III, the need to conserve judicial resources, the multiple ANDAs, and the relationship between Teva and Gate. On appeal, Teva argues that the Hatch-Waxman Act requires district courts to exercise jurisdiction in all declaratory judgment cases, so long as jurisdiction exists. According to Teva, the unequivocal language of 35 U.S.C. § 271(e)(5) overrides the general grant of discretion in 28 U.S.C. § 2201.

We disagree. Section 271(e)(5) (emphasis added) states that "the courts of the United States *shall,* to the extent consistent with the Constitution, have

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[4] On September 28, 2010, Teva advised the court of a subsequent stipulation the parties entered into on July 19, 2010 in the '841 patent infringement litigation. The parties agreed that the preliminary injunction would remain in effect until the '841 patent expires on November 25, 2010. This stipulation does not change our analysis in this case for two reasons. First, it does not affect jurisdiction at the outset of this appeal. Second, given that the stipulation is only relevant, if at all, until the expiration of the '841 patent on November 25, after that date the DJ patents would bar Teva from obtaining FDA approval earlier and marketing the generic form of donepezil covered by the Gate ANDA. To be sure, in this case, even if the DJ action resulted in a favorable outcome for Teva, the first-filer's 180-day exclusivity period would run after the '841 patent's expiration date.

subject matter jurisdiction." The Declaratory Judgment Act provides that "any court of the United States, upon the filing of an appropriate pleading, *may* declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a) (emphasis added). In our view, § 271(e)(5) speaks only to the power of a court to decide a case, not the prudence. Thus, while § 271(e)(5) clarifies the maximum extent of a court's jurisdiction, it does not govern how the district court may exercise its discretion under § 2201 in deciding whether to declare the rights of the litigants. *See MedImmune*, 549 U.S. at 136-37. Section 271(e)(5) thus leaves intact the discretion granted by § 2201 to decline jurisdiction over declaratory judgment actions. *Sony Elecs.*, 497 F.3d at 1288-89. We have thus upheld discretionary decisions declining jurisdiction when the declaratory judgment action was duplicative of other proceedings, the party instituted an action solely to enhance its bargaining power in negotiations, or when reexamination proceedings were pending. *Id.*; *see also EMC Corp. v. Norand Corp.*, 89 F.3d 807, 813-16 (Fed.Cir.1996), *overruled in part on other grounds*, *MedImmune*, 549 U.S. 118 (2007).

However, while the Declaratory Judgment Act does "confer on federal courts unique and substantial discretion" to decide whether to exercise jurisdiction, that discretion is not unbounded. *See MedImmune*, 549 U.S. at 136; *Sony Elecs.*, 497 F.3d at 1288. In exercising such discretion, the district court must typically consider the usefulness of the declaratory judgment remedy, the fitness of the case for resolution, and the purposes of the Declaratory Judgment Act. *Wilton v. Seven Falls Co.*, 515 U.S.

277, 286 (1995); *see also Serco Servs. Co. v. Kelley Co.*, 51 F.3d 1037, 1039 (Fed.Cir.1995). A district court abuses its discretion when (1) its decision is clearly unreasonable or arbitrary; (2) its decision is based on an erroneous conclusion of law; (3) the court's findings were clearly erroneous; or (4) the record contains no evidence upon which the court could rationally have based its decision. *Sony Elecs.*, 497 F.3d at 1288.

In this case, we conclude that it was an abuse of discretion to decline jurisdiction. At least two errors infect the district court's exercise of discretion under § 2201(a). First, as explained above, the district court erroneously concluded that it lacked subject matter jurisdiction, a factor it then relied upon in deciding to decline jurisdiction. The district court should not have considered whether it had subject matter jurisdiction in making the subsequent, discretionary decision of whether to exercise jurisdiction over the case. *See Wilton*, 515 U.S. at 286; *Sony Elecs.*, 497 F.3d at 1271. While a lack of subject matter jurisdiction would require the district court to dismiss the case, the existence of jurisdiction in itself is not probative of the relevant factors under § 2201(a), such as whether the declaratory judgment remedy will be useful or whether the case is fit for resolution.

Second, the district court's exercise of discretion is not supported by the facts. The district court's conclusion that the relationship between Teva and Gate, combined with the multiple ANDAs, amounted to thinly disguised, improper gamesmanship is not what the record shows. Nothing in the Hatch-Waxman Act bars a company from filing multiple

ANDAs covering different formulations of the same drug, as Teva (through Gate) did here. Nor was it improper for those ANDAs to be filed under different corporate names, particularly since this filing decision was made at the FDA's request. We agree with Teva that this case presents none of the typical factors that might warrant the exercise of discretion to decline jurisdiction. This case is not duplicative of other pending or decided litigation; in the absence of this action, the validity or infringement of the DJ patents will not be litigated. Further, as explained above, there is an actual controversy. A declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty and insecurity. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed.Cir.2007); *see also Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed.Cir.1993).

Because no "sound basis" for refusing to adjudicate this case has been shown, on remand this case should proceed absent additional facts that might warrant a contrary conclusion. *See Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed.Cir.2005); *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed.Cir.2004).

CONCLUSION

Because this case presents an actual controversy justiciable under Article III and no well-founded basis for declining jurisdiction has been established, we reverse the district court's dismissal for lack of subject matter jurisdiction. The case is remanded for further proceedings consistent with this opinion.

REVERSED AND REMANDED

APPENDIX B

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2009-1593

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff-Appellant,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants-Appellees.

Appeal from the United States District Court for the District of New Jersey in case no. 08-CV-2344, Chief Judge Garrett E. Brown, Jr.

ON MOTION

ORDER

Appellees move to vacate the court's decision and judgment of October 6, 2010 for mootness and to stay the issuance of the mandate. Appellant opposes, and appellees reply.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

DATE: December 10, 2010 FOR THE COURT

/s/ Jan Horbaly

Jan Horbaly
Clerk

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2009-1593

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff-Appellant,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants-Appellees.

JUDGMENT

ON APPEAL from the District Court for the District of New Jersey

CASE NO.: 08-CV-2344

This CAUSE having been heard and considered, it is

ORDERED AND ADJUDGED:

REVERSED AND REMANDED.

ENTERED BY ORDER
OF THE COURT

DATED: October 06, 2010 /s/ Jan Horbaly
Jan Horbaly, Clerk

ISSUED AS A MANDATE: DEC. 13, 2010

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 08-2344 (GEB)

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants.

MEMORANDUM OPINION

September 9, 2009

Mayra Velez Tarantino, Michael E. Patunas, Lite, Depalma, Greenberg & Rivas, LLC, Newark, NJ, for Plaintiff.

William J. Heller, McCarter & English, LLP, Newark, NJ, for Defendants.

BROWN, Chief Judge.

This matter comes before the Court on the renewed motion to dismiss for lack of subject matter jurisdiction (Doc. No. 20) filed by Defendants Eisai Co., Ltd. and Eisai Medical Research, Inc. ("Eisai").

In its Amended Complaint, Plaintiff Teva Pharmaceuticals USA ("Teva") through its Gate Pharmaceuticals ("Gate") division, seeks a declaratory judgment of noninfringement of four patents: U.S. Patent Nos. 5,985,864 ("the '864 patent"); 6,140,321 ("the '321 patent"); 6,245,911 ("the '911 patent"); and 6,372,760 ("the '760 patent"). This Court will refer to these four patents collectively as the "DJ patents." In its motion to dismiss, Eisai contends that this Court lacks subject matter jurisdiction because Teva's claims for declaratory judgment present no justiciable controversy. For the following reasons, Eisai's motion will be granted.

BACKGROUND

Resolution of Eisai's motion requires understanding of the complicated statutory scheme for the approval of new and generic drugs under the Hatch-Waxman Act.[1] As the Federal Circuit has often stated, the Hatch-Waxman Act aims to "balance two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed.Cir.2008) (quoting *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed.Cir.2002)).

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[1] The Hatch-Waxman Act is the title 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, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat.2066 (2003).

I. The Hatch-Waxman Act

The Hatch-Waxman Act requires that before a drug manufacturer can market a new drug, it must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") for approval. 21 U.S.C. § 355(a). In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1). Once the NDA is approved, the FDA lists this patent information with the approved drug in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1), 355(j)(A)(ii)(iii).

Generic drug manufacturers may obtain FDA approval for generic versions of previously-approved drugs by filing an Abbreviated New Drug Application ("ANDA"), without having to repeat the extensive testing required for a new drug application. *See* 21 U.S.C. § 355(j). When submitting an ANDA to the FDA, the Hatch-Waxman Act requires a generic manufacturer to make one of the following four certifications with respect to each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed (a "Paragraph I" certification), (2) that the patent has expired (a "Paragraph II" certification), (3) that the patent will expire on a specific date (a "Paragraph III" certification), or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the application is submitted" (a

"Paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). A company seeking to market a generic version of a listed drug prior to the expiration of the Orange Book-listed patents must file a Paragraph IV certification. The filing of a Paragraph III certification with respected to a listed patent, on the other hand, signifies that the FDA may wait until expiration of the named patent to approve the ANDA.

"In order to bring about early resolution of patent disputes between generics and pioneering drug companies, the [Hatch-Waxman] Act provides that the filing of a Paragraph IV Certification is an act of patent infringement." *Janssen*, 540 F.3d at 1356 (citing 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990)). Upon receiving notice from the ANDA filer of the Paragraph IV certification and its factual and legal bases, the NDA holder may bring an infringement suit on all, some, or none of the patents included in the certification. *Id.* If the NDA holder fails to bring suit on any of the patents subject to the Paragraph IV certification within 45 days of notice, the FDA may approve the ANDA. If the NDA holder files suit, FDA approval of the ANDA is subject to a 30-month stay.

More importantly for the instant matter, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification with respect to a listed patent shall enjoy a 180-day period of generic marketing exclusivity. This exclusivity period serves "to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible." *Caraco Pharm. Labs.,*

Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1283 (Fed.Cir.2008). The FDA may not approve a subsequent Paragraph IV ANDA until the expiration of the first-filer's exclusivity period. The first-filer may take advantage of the 180-day exclusivity period regardless of whether it actually establishes that the listed patents subject to the Paragraph IV certification are invalid or not infringed by the ANDA drug. *Janssen*, 540 F.3d at 1356.

"The start of the 180-day exclusivity period is triggered by the earlier of two events: (1) the first Paragraph IV ANDA filer's commercial marketing of a drug product; or (2) a court decision of noninfringement or invalidity." *Id.* at 1357 (citing 21 U.S.C. § 355(j)(5)(B)(iv)).[2] While only the first-filer may trigger its own exclusivity period by "hitting the market," subsequent-filers can trigger the first-filer's exclusivity period via a successful court judgment. *Id.*

Congress amended the Hatch-Waxman Act in 2003 to allow for an action pursuant to 28 U.S.C. § 2201 seeking a declaratory judgment that a listed

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[2] In December 2003, Congress amended the portion of the Hatch-Waxman Act regarding the triggering of the exclusivity period with new provisions establishing conditions under which the exclusivity period may be forfeited for various reasons. These new provisions, however, contain a grandfather clause "specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the [amendments] or to subsequent Paragraph IV ANDAs filed after the enactment of the [amendments] if the first Paragraph IV ANDA was filed prior to enactment of the [amendments]." *Janssen*, 540 F.3d at 1357 n. 2. Here, as discussed shortly, Ranbaxy Laboratories Ltd. filed the first ANDA for generic donepezil in August 2003, before the effective date of the relevant amendments. Therefore, these amendments do not apply to this case.

drug is invalid or not infringed by the drug for which an ANDA filer requests approval. Under the current statutory scheme, a Paragraph IV ANDA filer (whether a first-filer or a subsequent-filer) may "bring a declaratory judgment action for noninfringement or invalidity of the relevant listed patents against the patentee and NDA holder, if the patentee has not brought an infringement action within the 45-day notice period." *Janssen*, 540 F.3d at 1357 (citing 21 U.S.C. § 355(j)(5)(C)). Notably, "Congress extended federal court jurisdiction over these declaratory judgment actions 'to the extent consistent with the Constitution.' " *Id.* (quoting 35 U.S.C. § 271(e)(5)). Thus, a federal court's jurisdiction over such a declaratory judgment action depends upon whether the action presents an Article III case or controversy. *Id.* (citing *Caraco*, 527 F.3d at 1285).

II. Factual Background and Procedural History

In this matter, Eisai filed an NDA for donepezil hyrdochloride ("donepezil") for the treatment of Alzheimer's disease, and the FDA approved the NDA in 1996. Eisai markets its versions of donepezil as the prescription drug product Aricept®. Eisai listed five patents in the Orange Book for Aricept®: the four DJ patents at issue in this case, and U.S. Patent No. 4,895,841 ("the '841 patent").

In August 2003, Ranbaxy Laboratories Ltd. ("Ranbaxy") filed the first ANDA for generic donepezil. In its ANDA, Ranbaxy included a Paragraph III certification against the '841 patent, indicating its agreement to not market a generic version of Aricept® until that patent expires in November 2010. Against the four other listed patents-the DJ patents-the Ranbaxy ANDA made

Paragraph IV certifications. Despite the filing of these Paragraph IV certifications, Eisai elected not to bring an infringement action against Ranbaxy. Thus, although Eisai did not trigger any 30-month stay on FDA approval of Ranbaxy's ANDA, the Paragraph III certification forestalls FDA approval of the ANDA until after November 2010. Still, Ranbaxy's first-filer status as to its Paragraph IV certifications against the DJ patents made it eligible for the 180-day marketing exclusivity period upon FDA approval of its ANDA.

Plaintiff Teva filed its first donepezil ANDA in October 2004 ("first ANDA"). Teva's initial ANDA, like Ranbaxy's, included a Paragraph III certification against the '841 patent and Paragraph IV certifications as to the DJ patents. One year after filing this ANDA, in October 2005, Teva amended its ANDA to include a Paragraph IV certification claiming that the '841 patent is invalid for obviousness. Teva's Paragraph IV certification against the '841 patent in its amended ANDA allowed Teva to share in the 180-day exclusivity period with Ranbaxy, as both Teva and Ranbaxy were first-filers with regard to Orange Book patents for Aricept®. Upon receiving notice of the Paragraph IV certification against the '841 patent, Eisai filed a patent infringement suit against Teva in this Court claiming infringement of the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.*, No. 05-5727 (D.N.J.). By timely suing for infringement, Eisai secured a 30-month stay of FDA approval of Teva's first ANDA. Eisai did not file suit on the DJ patents.

In 2005, Teva filed a new, separate ANDA in the name of Gate Pharmaceuticals ("second ANDA" or

"Gate ANDA"). Teva's Amended Complaint in this matter identifies Gate merely as a division of Teva. (Am.Compl.¶ 1.) Both Teva and Gate share the same principal place of business, and there is no evidence that Gate is incorporated or otherwise exists separately from its status as a division of Teva.[3] This second Teva ANDA specified a different form of generic donepezil-employing a different active pharmaceutical ingredient-than stated in Teva's first ANDA. According to Teva, the FDA required a separate ANDA because the form of donepezil encompassed in the second ANDA differs from that described in the first ANDA, and the FDA also "requested that [the second ANDA] be filed in a different name to avoid confusion between the two products." (Teva Br. at 5.) The initial second ANDA included Paragraph III certifications against all five listed patents for Aricept®.

Nearly two years after filing the second ANDA, Gate amended the second ANDA to include Paragraph IV certifications against all five listed Aricept® patents. Upon notice of the amendment, in

[3] Courts have recognized that Gate is merely an unincorporated division of Teva. *See, e.g.*, *Eli Lilly & Co. v. Sicor Pharms., Inc.*, No. 06-238, 2007 WL 1245882, at *3 (S.D.Ind. Apr.27, 2007) ("In addition to generic drug sales, Teva USA sells drugs through its branded division, Gate Pharmaceuticals."); *In re Die t Drugs Prods. Liab. Litig.*, 990 F.Supp. 834, (J.P.M.L.1998) (naming "Teva Pharmaceuticals, USA, Inc., and its sales division Gate Pharmaceuticals"). Indeed, the website for Gate Pharmaceuticals states that "Gate Pharmaceuticals was created in 1990 to market innovative pharmaceutical products in the United States. Gate Pharmaceuticals is a division of Teva Pharmaceuticals USA, a subsidiary of Teva Pharmaceutical Industries, Ltd., Israel's leading pharmaceutical company." *See* http://www.gatepharma.com/.

November 2007, Eisai sued Teva and Gate for infringement of the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.,* No. 07-5489 (D.N.J.). Until that time, the only issue litigated in the first infringement action, regarding the first Teva ANDA, was Teva's affirmative defense of obviousness with regard to the '841 patent. In April 2007, Teva stipulated that its generic drug would constitute infringement of various claims of the '841 patent, unless Teva proves in the *Eisai v. Teva* litigation that the '841 patent is invalid or unenforceable. (No. 05-5727, Doc. No. 65.) In late 2007, Teva amended its answers in both '841 patent infringement actions to add the affirmative defense of inequitable conduct and withdraw the obviousness defense. The two '841 patent infringement actions were subsequently consolidated in early 2008. (No. 05-5727, Doc. No. 113.)

The 30-month stay of approval of Teva's first ANDA triggered by Eisai's timely infringement suit on the '841 patent expired in April 2008. The FDA approved Teva's first ANDA on April 28, 2008. Teva had previously notified Eisai that it intended to launch a generic version of Aricept® immediately upon receiving final approval of its first ANDA. Prior to the FDA's approval of the first ANDA, Eisai filed a motion for a preliminary injunction to prevent Teva from marketing any form of generic donepezil. In the briefing on Eisai's preliminary injunction motion, Teva made no reference to any additional restraints on its ability to market generic donepezil, such as the four other listed patents. The Honorable Harold A. Ackerman, Senior United States District Judge, granted Eisai's motion for a preliminary injunction in

March 2008.[4] The preliminary injunction entered by Judge Ackerman restrained and enjoined Teva and Gate from marketing *any* drug product containing donepezil hyrdochloride as claimed in the '841 patent. *Eisai Co. v. Teva Pharms. USA, Inc.*, Nos. 05-5727/07-5489, 2008 WL 1722098, at *13 (D.N.J. Mar.28, 2008) (specifically naming Teva and Gate as subject to the injunction). This preliminary injunction remains in effect, as the '841 patent litigation remains pending. Therefore, Teva and Gate are presently precluded from marketing any form of generic donepezil until at least November 2010, at the expiration of the '841 patent, and this bar to market entry will remain in effect unless Teva ultimately prevails in the '841 patent case.

In May 2008, Teva filed the instant declaratory judgment action regarding the four DJ patents. As Teva's initial Complaint acknowledged, Eisai had previously filed statutory disclaimers, pursuant to 35 U.S.C. § 253, with the U.S. Patent and Trademark Office regarding two of the DJ patents, the '321 and '864 patents. (Compl. ¶ 10; Gill Decl., Ex. 1.) Eisai's formal disclaimers of these patents, in 2006 and 2007 respectively, "ha[ve] the effect of canceling the claims from the patent[s] and the patent[s][are] viewed as though the disclaimed claims had never existed in the patent[s]." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed.Cir.1996). Therefore, based on the disclaimers, Eisai "has no further right to enforce the claims that have been disclaimed, or to obtain a reissue of any of

[4] The '841 patent infringement actions, along with the instant matter, were initially assigned to Judge Ackerman. Judge Ackerman presided over these cases for several years. In August 2009, all of these cases were reassigned to the undersigned.

these claims." *Merck & Co. v. Apotex, Inc.*, No. 06-5789, 2007 WL 4082616, at *5 (D.N.J. Nov.15, 2007). Despite the Paragraph IV certifications filed against the two other DJ patents, the '911 and '760 patents, Eisai has never brought suit against Teva or any other ANDA filer to enforce these patents.

In its initial complaint in this matter, Teva sought a declaratory judgment of noninfringement of all four DJ patents with respect to the second ANDA filed in Gate's name (Counts I-IV), and of noninfringement with respect to the two non-disclaimed DJ patents, the '911 and '760 patents, with respect to Teva's first ANDA (Counts V-VI). Regarding Teva's first ANDA, the initial complaint alleged that because Eisai did not file suit on the non-disclaimed DJ patents, but they remain listed in the Orange Book, Teva faced a restraint on its ability to commercially market generic donepezil because of the potential risk of future suit on those patents by Eisai. With regard to the second ANDA filed in Gate's name, however, Teva asserted two distinct injuries justifying declaratory judgment jurisdiction: 1) restraint on its ability to market generic donepezil based on potential risk of future suit; and 2) that without a judgment of non-infringement on all four DJ patents, Gate would be unable to win FDA approval of its ANDA ("FDA-approval-blocking injury"). This latter argument amounts to the theory that without a court decision on the four DJ patents, Ranbaxy's exclusivity period with regard to those patents will not be triggered, thus forestalling FDA approval of the Gate ANDA.

After being served with the complaint, Eisai informed Teva that it had disclaimed the '864

and '321 patents, and offered to enter into a binding covenant-not-to-sue on any of Teva's ANDA products based on the '911 and '760 patents. Eisai subsequently filed a motion to dismiss for lack of subject matter jurisdiction. After Eisai filed its motion, the parties negotiated a covenant-not-to-sue on the '911 and '760 patents. In the covenant-not-to-sue, Eisai unconditionally agreed that it would not assert the '911 and '760 patents against Teva or its successors with respect to any generic donepezil formulation described in both Teva ANDAs. (Michael Decl., Ex. 34.) Teva subsequently dismissed Counts V and VI of the initial complaint, as those claims concerned the first Teva ANDA and the potential risk of suit on the patents now subject to the covenant-not-to-sue.

However, instead of responding to the remainder of Eisai's motion to dismiss, Teva filed an Amended Complaint. The Amended Complaint deleted all meaningful reference to Teva itself and Teva's first ANDA, omitted any allegation of commercial restraint based on risk of future suit, and only raised allegations made by Gate as a division of Teva with regard to the second ANDA. In the Amended Complaint, Teva clearly alleges FDA-approval-blocking injury as the sole basis for declaratory judgment jurisdiction, thereby requesting a judgment of non-infringement as to all four DJ patents. Teva's Amended Complaint states that

> [e]ven though Eisai Co. Ltd has disclaimed the '864 and '321 patents and has provided GATE with a covenant not to sue with respect to the '911 and '760 patents, they remain in the FDA Orange Book. As a result, GATE is suffering actual injury

> because it will not be able to obtain final FDA approval of its ANDA as a result of 21 U.S.C. § 355(j)(5)(B)(4). A court decision finding the patents not infringed is the only way to redress this injury.

(Am.Compl.¶ 14.) Shortly after Teva filed its Amended Complaint, Eisai filed the instant renewed motion to dismiss.

ANALYSIS

I. Standard of Review

A. *Rule 12(b)(1)*

Eisai has renewed its motion to dismiss Teva's Amended Complaint for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Because Eisai presents a factual challenge to this Court's subject matter jurisdiction by challenging Teva's jurisdictional allegations, this Court "may consider and weigh evidence outside the pleadings to determine if it has jurisdiction." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir.2000); *see also Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *14 (D.N.J. Dec.20, 2007). In resolving a factual attack to jurisdiction, "no presumptive truthfulness attaches to the nonmovant's allegations, and the existence of disputed material facts will not preclude the Court from evaluating the merits of jurisdictional claims." *Merck*, 2007 WL 4082616, at *4 (citing *Robinson v. Dalton*, 107 F.3d 1018, 1021 (3d Cir.1997)). As the nonmovant, Teva bears the burden of persuasion as to the existence of subject matter jurisdiction. *See, e.g.*, *Merck*, 2007 WL 4082616, at *3.

B. *Declaratory Judgment Jurisdictional Standard*

Congress has extended declaratory judgment jurisdiction under the Declaratory Judgment Act to Paragraph IV ANDA filers seeking to establish noninfringement or invalidity of listed patents "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The Declaratory Judgment Act provides that "[i]n a case of *actual controversy* within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added).

No bright-line rule governs whether a case presents an actual controversy. *See PharmaNet, Inc. v. DataSci Ltd. Liab. Co.*, No. 08-2965, 2009 WL 396180, at *4 (D.N.J. Feb.17, 2009). The Supreme Court has required only that the dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). Because the Hatch-Waxman Act authorizes declaratory judgment actions to the full extent consistent with the Constitution, this Court must apply the all-the-circumstances test for declaratory judgment jurisdiction "guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy. In particular, an action is justiciable under Article III

only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation." *Caraco*, 527 F.3d at 1291 (internal citations omitted). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cos. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

MedImmune reiterated this "all-the-circumstances" standard and rejected the exclusive "reasonable apprehension of suit" test previously applied by the Federal Circuit. *See, e.g.*, *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed.Cir.2007). "Following *MedImmune,* proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy." *Caraco*, 527 F.3d at 1291; *see also PharmaNet*, 2009 WL 396180, at *4 (observing that all-the-circumstances test did not make reasonable apprehension of suit irrelevant). The declaratory judgment plaintiff bears the burden of proof to show jurisdiction at the time of filing and throughout the case. *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed.Cir.2007). Even if this Court finds the constitutional prerequisites to jurisdiction to be satisfied, it retains the discretion pursuant to the Declaratory Judgment Act to decline declaratory judgment jurisdiction. *See, e .g.*, *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995) ("[D]istrict courts

possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites.").

II. Teva's Alleged FDA-Approval-Blocking Injury

Because Eisai has disclaimed two of the DJ patents, and has entered into a binding covenant not to sue Teva on the other two DJ patents, Eisai has no right to enforce the DJ patents. Teva faces no restraint on its ability to market generic donepezil based on the potential that Eisai may bring suit to prevent such marketing based on the DJ patents. Teva amended its complaint in this matter to remove any allegation of such injury based on reasonable apprehension of suit. Therefore, on first blush, there would appear to be an absence of "adverse legal interests" between Teva and Eisai "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127. Indeed, if "a threat of suit was the only action allegedly taken by [Eisai] that effectively excluded [Teva] from the marketplace, the covenant not to sue would moot [Teva's] case and divest [this Court] of Article III jurisdiction." *Caraco*, 527 F.3d at 1296.

However, Teva asserts a different form of injury at the hands of Eisai: FDA-approval-blocking injury. Based on Teva's first ANDA, Teva shares a 180-day exclusivity period on the marketing of generic donepezil with Ranbaxy. Ranbaxy's exclusivity period results from its first-filed Paragraph IV certifications against the DJ patents, while Teva shares in that period based on its first-filed, if belated, Paragraph IV certification against the '841 patent. The exclusivity period may be triggered either by the

commercial marketing of the generic drug product by the exclusivity holder, or by a court judgment-secured by the first-filer or subsequent filers-of noninfringement or invalidity of the patent against which a Paragraph IV certification was filed. *Caraco*, 540 F.3d at 1357 (citing 21 U.S.C. § 355(j)(5)(B)(iv)). Only after the 180-day exclusivity period expires may the FDA approve a subsequently-filed ANDA, and only with such FDA approval may that ANDA filer market its generic drug.

At the present time, neither Ranbaxy nor Teva may trigger their shared 180-day exclusivity period prior to the expiration of the '841 patent in November 2010. Ranbaxy filed a Paragraph III certification against the '841 patent, thereby forestalling FDA approval of its ANDA until the expiration of that patent. While the FDA approved Teva's first ANDA in April 2008, Judge Ackerman shortly thereafter issued a preliminary injunction precluding Teva from marketing any form of generic donepezil as claimed by the '841 patent. That injunction remains in effect as the parties litigate Eisai's '841 patent infringement suit.

For these reasons, only a court judgment of noninfringement or invalidity of the DJ patents could trigger Ranbaxy's exclusivity period at this time, and only a similar judgment as to the '841 patent could trigger Teva's exclusivity period. Absent a court judgment, the exclusivity period will not commence, at least prior to the expiration of the '841 patent, and concomitantly, the FDA will not approve any subsequent ANDAs, thereby preventing subsequent ANDA filers from marketing generic versions of donepezil. Teva, through its unincorporated Gate

division, is also a subsequent ANDA filer for donepezil. Teva seeks a declaratory judgment of noninfringement as to the DJ patents so that Ranbaxy's exclusivity period may be triggered, thus lifting the barrier to FDA approval of the Gate ANDA and thereby allowing Teva to market the Gate ANDA version of generic donepezil.

Teva alleges that because Eisai listed the DJ patents in the Orange Book and failed to bring suit on them when challenged by Paragraph IV certifications, the patents' continued presence in the Orange Book without the ability for a court judgment prevents the FDA from approving the Gate ANDA under the Hatch-Waxman Act In other words, Teva argues that Eisai is injuring Teva by effectively excluding Teva from the market. According to Teva, Eisai's infliction of this FDA-approval-blocking injury has sufficient immediacy and reality to justify declaratory judgment jurisdiction.

III. *Caraco* and *Janssen*

In *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, the Federal Circuit recognized that FDA-approval-blocking injury could establish declaratory judgment jurisdiction for a suit brought by a subsequent Paragraph IV ANDA filer for a judgment of noninfringement with respect to patents for which the patent holder has entered into a covenant-not-to-sue. Applying the "all-the-circumstances" standard reaffirmed in *MedImmune*, the Federal Circuit held that "[i]n claiming that it has been denied the right to sell non-infringing generic drugs, [the generic manufacturer] has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy." *Caraco*, 527

F.3d at 1293-94. Teva vigorously contends that *Caraco* controls here, and declaratory judgment jurisdiction exists, because Teva stands in the same position as the plaintiff in *Caraco*.

To determine whether *Caraco* dictates the result here, this Court must consider the specific factual circumstances at issue in *Caraco*. A court in the District of Delaware recently summarized the facts of *Caraco* as follows:

> In *Caraco*, ... the patent holder, Forest Laboratories, Inc. ("Forest"), listed multiple patents in the Orange Book in relation to its NDA. Specifically, there were two Orange Book patents: the '712 patent, which expires in 2012, and the '941 patent, which expires in 2023. Also, ... there were two Paragraph IV ANDA filers: Ivax Pharmaceuticals, Inc. ("Ivax") filed the first ANDA, and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed the second ANDA. Both Ivax's ANDA and Caraco's ANDA pertained to the two listed patents. However, after Ivax filed its ANDA, Forest chose to sue only on the '712 patent, which was ultimately found valid, infringed, and enforceable. Later, after Caraco filed its ANDA, Forest sued Caraco on only the '712 patent, granting Caraco a covenant-not-to-sue on the '941 patent. In these circumstances, even if Caraco were to have achieved victory on the '712 patent, it would have been unable to go to market until Ivax completed its 180-day exclusivity period on the '941 patent, which could be no earlier than 181 days after the expiration of the '712 patent. Hoping to trigger Ivax's 180-day exclusivity on the '941 patent, and hence put itself in a position

> to enter the market earlier, Caraco brought a declaratory judgment action for non-infringement of the '941 patent.

Dey, L.P. v. Sepracor, Inc., 595 F.Supp.2d 355, 359-60 (D.Del.2009) (internal citations to *Caraco* omitted).

On these facts, the Federal Circuit concluded that Caraco had standing because Forest's listing of the DJ patents in the Orange Book "effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that [the listed patents] are invalid or not infringed by its generic drug." *Caraco*, 527 F.3d at 1292-93; *see also id.* at 1292 ("[W]here the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely."). A favorable declaratory judgment "would clear the path to FDA approval that Forest's actions would otherwise deny Caraco — namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) to activate Ivax's exclusivity period." *Id.* at 1293. The Federal Circuit further held that Caraco's action was ripe because the issues were fit for judicial decision and because withholding judicial consideration would have an immediate and substantial impact on Caraco by creating a potential for lost profits. *Id.* at 1295-96. Finally, the Federal Circuit found that Forest's covenant-not-to-sue did not render Caraco's declaratory judgment claim moot because Caraco demonstrated that the Orange Book-listing of the patent on which Forest agreed not to sue effectively prevented Caraco from entering the drug market in "a manner that is unique to the Hatch-Waxman context." *Id.* at 1296. As the Federal

Circuit stated, under the Hatch-Waxman Act "an NDA holder's covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA." *Id.* at 1296.

The Federal Circuit Later declined to apply *Caraco* under factual circumstances where the first Paragraph IV filer and the subsequent filer, but for the first-filer's exclusivity period, faced the same limitations on entering the market. In *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, the NDA holder listed three patents in the Orange Book. The first ANDA filer, which coincidentally happened to be Teva, filed Paragraph IV certifications as to two of the patents and a Paragraph III certification as to the third. Apotex, Inc. ("Apotex"), a subsequent ANDA filer who had filed Paragraph IV certifications against all three patents, sought a declaratory judgment of noninfringement regarding the two patents against which Teva filed its Paragraph IV certification, so as to trigger Teva's exclusivity period. The NDA holder granted Apotex covenants-not-to-sue as to the two patents for which Apotex sought a declaratory judgment.

The Federal Circuit agreed that the facts of *Caraco* and *Janssen* were substantially similar, but for one crucial difference: Apotex stipulated to the validity, infringement, and enforceability of the third listed patent. Thus, even if Apotex won the declaratory judgment it sought, it could not obtain FDA approval of its ANDA until the expiration of the patent to which it stipulated validity and enforceability. *See Janssen*, 540 F.3d at 1361. As the district court in *Dey* aptly stated, "[a]s a result of the stipulation, Apotex placed itself on equal footing with

Teva with respect to the earliest date it could conceivably enter the market." *Dey*, 595 F.Supp.2d at 362 (following *Caraco* and concluding that declaratory judgment jurisdiction existed because the court found "nothing equivalent to Apotex's stipulation" in the facts before it). The injury suffered by Apotex in *Janssen* was not the injury identified in *Caraco*, as plaintiff in *Caraco* sought to trigger the first-filer's exclusivity period "*at a time when [the first-filer] could obtain FDA approval and then launch its product.*" *Janssen*, 540 F.3d at 1361 (emphasis in original). Apotex could not have been "blocked from entering the market by an invalid patent" because it stipulated to that patent's validity. *Id.* The Federal Circuit concluded that the only harm Apotex suffered was its inability to market its generic drug *during* Teva's exclusivity period, "a result envisioned by the Hatch-Waxman Act," and "not a cognizable Article III controversy." *Id.* While the Federal Circuit in *Janssen* reaffirmed the holding in *Caraco*, stating that *Caraco* was "supported by Supreme Court precedent," *id.* at 1363, the court nonetheless distinguished *Caraco* and concluded that Apotex's claim did not present a justiciable Article III controversy. *Id.* Here, Eisai argues for the same treatment of *Caraco* based on the unique facts of this case.

IV. *Caraco* is Distinguishable, and This Court Has No Jurisdiction over Teva's Declaratory Judgment Claims

While many of the facts in the instant matter are similar to those that compelled the Federal Circuit to find jurisdiction in *Caraco*, several crucial distinctions exist between the circumstances Caraco encountered and those that Teva faces here. First,

the dormant Ranbaxy exclusivity period, which indefinitely delays FDA approval of the Gate ANDA, does not present the only barrier to market entry by Teva under either of its ANDAs. The inability to win approval of the Gate ANDA does not prevent Teva from marketing a form of generic donepezil, because the FDA previously approved Teva's first ANDA. Gate is merely an unincorporated division of Teva, and appears to have no legal status independent of Teva. Indeed, Teva is the only named plaintiff in this matter, and brings this suit "through its Gate Pharmaceuticals division." (Am. Compl. at 1.) Teva filed the second ANDA in Gate's name, allegedly at the FDA's request, only to avoid confusion, but this separate filing does not change the fact that Teva and Gate are essentially equivalent. Teva goes to great lengths in its brief to obscure and downplay the relationship between Teva and Gate, but Teva simply cannot claim that its asserted FDA-approval-blocking injury as to the Gate ANDA has wholly excluded Teva from the market in the same manner as Caraco was "effectively prevent[ed] from entering the drug market." *Caraco*, 527 F.3d at 1296.

Any alleged FDA-approval-blocking injury suffered by Teva through Gate fails to present a substantial controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment" *MedImmune*, 549 U.S. at 127. Teva seeks to trigger Ranbaxy's exclusivity period so as to accelerate approval of the Gate ANDA, but overlooks the fact that Teva itself shares in that exclusivity period based on its first-filed Paragraph IV certification against the '841 patent. Thus, the FDA cannot approve the Gate ANDA until Teva's *own* exclusivity period expires, aside from any impact of

Ranbaxy's shared exclusivity period. Teva cannot presently exhaust its exclusivity period, or invoke it by marketing generic donepezil and then waiving the exclusivity period to facilitate quicker approval of the Gate ANDA, because the preliminary injunction issued by Judge Ackerman precludes Teva from marketing *any* version of generic donepezil as covered by the '841 patent. The preliminary injunction specifically applies to Gate. The preliminary injunction therefore presents a barrier to Teva's market entry not found in *Caraco*, and one that deprives any hypothetical FDA-approval-blocking injury of the requisite immediacy and reality to warrant declaratory judgment jurisdiction.

Moreover, the preliminary injunction places Teva and Ranbaxy on an "equal footing" with respect to the Gate ANDA. *Dey*, 595 F.Supp.2d at 362. *Janssen* does not directly control because Teva itself has not stipulated to the enforceability of the '841 patent. Indeed, Teva opposed the entry of the preliminary injunction and continues to challenge the enforceability of the '841 patent in the *Eisai v. Teva* litigation. However, the distinction drawn in *Janssen* has persuasive force here because the circumstances in the instant matter place Teva and Ranbaxy in the same position with regard to the Gate ANDA as were Apotex and Teva in *Janssen*. Due to Ranbaxy's Paragraph III certification, the relationship between Teva and Gate, and the impact of the preliminary injunction against Teva and Gate in the '841 action, at this time both Teva (through Gate) and Ranbaxy cannot launch their generic versions of Aricept® until the expiration of the '841 patent. Thus, unlike the injury in *Caraco*, the harm to Teva from the delay in approval of the Gate ANDA does not result from the

inability to trigger the Ranbaxy exclusivity period absent a court judgment on the DJ patents. Rather, as in *Janssen*, any delay occasioned here by Teva's inability to market the Gate version during Ranbaxy's exclusivity period, once that period is triggered, results from the operation of the Hatch-Waxman Act and its grant of an exclusivity period, not any act by Eisai.

Teva contends that because the Gate ANDA concerns a different product than the first ANDA, the approval of that first ANDA makes no difference here, and Teva requires a declaratory judgment to redress the independent harm it suffers due to the inability to trigger the Ranbaxy exclusivity period. However, the preliminary injunction explicitly applies to Teva and Gate, and at this time has the same effect on Teva as Ranbaxy's Paragraph III certification does on Ranbaxy: Teva, through Gate, cannot market any form of generic donepezil, regardless of the impact of Ranbaxy's exclusivity period on eventual FDA approval of the Gate ANDA. Eisai and Teva are currently litigating the enforceability of the '841 patent, and *if* Teva ultimately prevails in that action, the preliminary injunction will be lifted. This Court expresses no opinion on the merits of the parties' arguments in the '841 patent action and the potential outcome of that case. However, because one may only speculate at this time 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 potential injury alleged by Teva here lacks the sufficient immediacy and reality required to establish declaratory judgment jurisdiction. Teva must show that declaratory judgment jurisdiction existed at the time

of filing and at all stages of review. *See, e.g.*, *Janssen*, 540 F.3d at 1360; *PharmaNet*, 2009 WL 396180, at *3. Even if this Court could possibly exercise jurisdiction in the future over Teva's claims for declaratory judgment, jurisdiction is wanting at this time.

Teva does not allege the same FDA-approval-blocking injury found sufficient for declaratory judgment jurisdiction in *Caraco*. This Court therefore will decline to extend *Caraco* to the different, unique facts of this case. Other courts, including a court in this District, have similarly declined to apply *Caraco* outside of the factual and legal context presented in that case. *See Dr. Reddy's Labs., Ltd. v. AstraZeneca AB*, No. 08-2496, 2008 WL 4056533, at *5-6 (D.N.J. Aug.28, 2008) (finding *Caraco* inapplicable to amended version of Hatch-Waxman Act); *Ivax Pharms., Inc. v. AstraZeneca AB*, No. 08-2165, 2008 WL 4056518, at *4-5 (D.N.I. Aug. 28, 2008) (same). For the same reasons that the covenant-not-to-sue defeats declaratory judgment jurisdiction on the facts of this case with regard to the '911 and '760 patents, Eisai's statutory disclaimers of the '864 and '321 patents prevent any substantial controversy regarding those patents. *See Merck*, 2007 WL 4082616, at *5 (finding, post-*MedImmune*, no declaratory judgment jurisdiction for claims regarding disclaimed patents); *see also Belk, Inc. v. Meyer Corp.*, No. 07-168, 2008 WL 2704792, at *3-4 (W.D.N.C. July 7, 2008) (same). This Court concludes that this case presents no justiciable Article III controversy, because under all the circumstances of this case, the facts do not "show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and

reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127.

Even if the jurisdictional requirements of *MedImmune* were satisfied, this Court would exercise its broad discretion pursuant to the Declaratory Judgment Act to decline jurisdiction. *See MedImmune*, 549 U.S. at 136; *Wilton*, 515 U.S. at 286-87. For the same reasons stated above with regard to Article III jurisdiction, this Court concludes that declining jurisdiction would be consistent with the purposes of the Declaratory Judgment Act and properly conserve judicial resources. Furthermore, the particular circumstances of this case, including the multiple ANDAs and the relationship between Teva and Gate, persuade this Court that the exercise of jurisdiction is unwarranted.

CONCLUSION

For the foregoing reasons, this Court will grant Eisai's renewed motion to dismiss for lack of subject matter jurisdiction (Doc. No. 20). An appropriate form of order accompanies this memorandum opinion.

APPENDIX E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 08-2344 (GEB)

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants.

ORDER

September 9, 2009

This matter having come before the Court on the renewed motion to dismiss for lack of subject matter jurisdiction filed by Defendants Eisai Co., Ltd. and Eisai Medical Research, Inc. ("Eisai"); and the Court having reviewed the parties' submissions and decided the motion without oral argument pursuant to Federal Rule of Civil Procedure 78; and for the reasons set forth in the accompanying Memorandum Opinion;

IT IS THIS 9th day of September, 2009,

ORDERED that Eisai's motion to dismiss (Doc. No. 20) is GRANTED.

The Clerk shall mark this matter closed.

/s/ Garrett E. Brown, Jr.
Garrett E. Brown, Jr.
Chief Judge
United States District Court

APPENDIX F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 08-2344 (GEB)

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants.

DOCKET ENTRY ORDER

December 21, 2010

12/21/2010 *** Civil Case Terminated. (DD,)
(Entered: 12/21/2010)

APPENDIX G

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2009-1593

TEVA PHARMACEUTICALS USA, INC.,
THROUGH ITS GATE PHARMACEUTICALS DIVISION,
Plaintiff-Appellant,

v.

EISAI CO., LTD. and EISAI MEDICAL RESEARCH, INC.,
Defendants-Appellees.

Appeal from the United States District Court for the District of New Jersey in case no. 08-CV-2344, Chief Judge Garrett E. Brown, Jr.

December 6, 2010

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the

Appellees, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 13, 2010.

FOR THE COURT,

/s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 12/06/2010

APPENDIX H

UNITED STATES CODE (2000 & Supp. II 2003)
TITLE 21—Food and Drugs
CHAPTER 9—Federal Food, Drug, and Cosmetic Act
SUBCHAPTER V—Drugs and Devices
PART A—Drugs and Devices

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration

date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which

information is required to be filed under paragraph (1) or subsection (c) of this section—

(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; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) (A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to

engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

(4) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced

to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(c) Period for approval of application; period for, notice, and expedition of hearing; period of issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) Approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) Give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the

drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective

immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be

brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the

person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective

before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1,

1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such

conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it

purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of

substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the

facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon

such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to

assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3) (A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after

receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2) (A)An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii) (I) if the listed drug referred to in clause (i) has only one active ingredient, information to show

that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph

(C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(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; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) (i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a

drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance

office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C) (i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D) (i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the

first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5) (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii),

the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28,

for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of

the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7) (A) (i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary

determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a

single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on

the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of Title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the

extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for

a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and

notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

APPENDIX I

UNITED STATES CODE
TITLE 28—Judiciary and Judicial Procedure
PART VI—Particular Proceedings
CHAPTER 151—Declaratory Judgments

§ 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, or section 351 of the Public Health Service Act.

APPENDIX J

UNITED STATES CODE
TITLE 35—Patents
PART III—Patents and Protection of Patent Rights
CHAPTER 28—Infringement of Patents

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory

infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e) (1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C) (i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product

involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a

certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6) (A) Subparagraph (B) Applies, in lieu of paragraph (4), in the case of a patent--

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive

remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f) (1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.