Appeal No. 2009-1593

United States Court of Appeals

for the

Federal Circuit

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.

NON-CONFIDENTIAL BRIEF FOR DEFENDANTS-APPELLEES

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CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, Bruce M. Wexler, counsel for Defendants-Appellees, Eisai Co., Ltd. and Eisai Medical Research, Inc., certifies the following:

1. The full name of every party represented by me is:

   Eisai Co., Ltd.
   Eisai Medical Research Inc.

2. The names of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   Eisai Co., Ltd.
   Eisai Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me are:

   In 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 percent or more of the stock of Eisai Co., Ltd.

4. The names of all law firms and partners or associates that appeared for the parties now represented by me in the trial court or are expected to appear in this court are:

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STATEMENT OF RELATED CASES

The four patents raised in this declaratory judgment action are also the subject of a later-filed declaratory judgment action by a subsequent generic application filer as to which a motion to dismiss is pending. *Apotex Inc. v. Eisai Inc.,* No. 09-cv-00477 (M.D.N.C.).

JURISDICTIONAL STATEMENT

The district court had jurisdiction to determine subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). *See, e.g.*, *Barrett v. Nicholson*, 466 F.3d 1038, 1045 (Fed. Cir. 2006) ("a court always has jurisdiction to determine its own jurisdiction") (internal quotations omitted). This Court has jurisdiction to review that decision under 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court correctly determined that no Article III case or controversy existed in Appellant's declaratory judgment action where:

(i) two patents had been disclaimed;

(ii) the other two patents were not enforceable because they were subject to an express covenant not to sue confirming several years in which no threats or suits had been brought on them;

(iii) the declaratory judgment action patents were not in fact excluding Appellant from the market, and Appellant's inability to presently market a generic drug was due to an injunction based on a different patent not in suit and to Appellant's own knowing and voluntary actions; and

(iv) Appellant's desire to use the court as a vehicle for an advisory opinion to trigger the 180-day exclusivity period of a non-party, at a time when neither that party nor Appellant could enter the market, was not an injury cognizable under Article III of the Constitution or a controversy between Eisai and Appellant.

2. In the alternative, whether the district court abused its discretion, conferred by the Declaratory Judgment Act, to decline proceeding in this action in light of the injunction against Appellant and the circumstances surrounding Appellant's generic drug application filings.

STATEMENT OF THE CASE

The district court determined that no justiciable controversy existed between Appellant Teva Pharmaceuticals USA, Inc. ("Teva") and Eisai in an action brought by Teva for a declaratory judgment of non-infringement of four Eisai 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") ("the DJ patents"). The district court further concluded that, even if the jurisdictional requirements were satisfied, the underlying purpose of the Declaratory Judgment Act and considerations of judicial resources made it appropriate to decline jurisdiction. Consequently, the district court dismissed Teva's declaratory judgment action.

STATEMENT OF THE FACTS

Because Teva's statement of the facts is incomplete and interspersed with unsupported argument, Eisai supplies the following background statement of facts.

A. The Hatch-Waxman Act

This litigation involves the Hatch-Waxman Act[1] governing the Food and Drug Administration's ("FDA's") approval of new and generic drugs. The Act balances two competing policy interests: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Under the Hatch-Waxman Act, an innovator 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 list patents with the FDA may subject an innovator drug company to various penalties.

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1 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), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003). Unless otherwise noted, all statutory references are to the codified pre-2003 version of the Hatch-Waxman Act.

E.g., id. § 355(e)(4); 21 C.F.R. § 314.53(b), (c), § 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).

The Hatch-Waxman Act also permits an Abbreviated New Drug Application ("ANDA") for generic drug makers. 21 U.S.C. § 355(j). In an ANDA, a generic drug manufacturer may rely on the safety and efficacy data generated by the innovator company (usually costing hundreds of millions of dollars) and show bioequivalence of the generic drug to the innovator drug. 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv), (j)(8)(B).

In the ANDA, a generic drug manufacturer must submit one of the following four certifications as to each patent listed in the Orange Book for the listed 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;
> (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.

If a manufacturer seeks to market a generic version of a listed drug before the expiration of a patent listed in the Orange Book covering that drug, the

company must file a Paragraph IV Certification. By contrast, a Paragraph III Certification with respect to a listed patent means that the ANDA will not be approved until the expiration of the named patent.

A Paragraph IV Certification filer must provide notice to the patent owner and NDA holder with "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II). If the patentee sues within 45 days, the FDA's approval of the ANDA is automatically stayed for 30 months unless an adverse judgment is entered sooner. 21 U.S.C. § 355(j)(5)(B)(iii).

Under the Hatch-Waxman Act, the first ANDA applicant to file a Paragraph IV Certification is eligible for a 180-day period of generic marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv). During this period, the FDA may not approve a later-filed ANDA that is based on the same NDA. *Id.* The 180-day exclusivity period encourages the early filing of generic drug applications and is a component of "the incentive structure adopted by the Congress." *E.g., Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006).

The 180-day exclusivity period may be triggered by either of two events: (1) a first-filer's commercial marketing of its generic drug, or (2) a final court decision finding the patents as to which the Paragraph IV Certification was made

invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv).[2] Pursuant to the Hatch-Waxman Act, a subsequent Paragraph IV ANDA filer may market 181 days thereafter.

The Hatch-Waxman Act authorizes a civil action, under 28 U.S.C. § 2201, 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). If the patent owner has not brought an infringement action against a Paragraph IV ANDA filer within 45 days of receiving a notice of the Paragraph IV Certification, the ANDA filer may bring an action for a declaratory judgment that the relevant listed patent is invalid or not infringed, "to the extent consistent with the Constitution." 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5).

B. Patents

In its NDA for Aricept®, Eisai listed five patents: U.S. Patent No. 4,895,841 ("the '841 patent") and the four DJ patents. (A104.) The '841 patent is directed to donepezil, the active ingredient in Aricept®, and its use to

2 The MMA, enacted on December 8, 2003, amended the Hatch-Waxman Act's provisions governing the commencement of the 180-day exclusivity period. Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066, 2457-60; 21 U.S.C. § 355(j)(5)(D). The MMA amendments do not apply if (as here) a generic drug company had filed a Paragraph IV ANDA for the listed drug prior to the MMA's enactment. Pub. L. No. 108-173, § 1102(b), 117 Stat. 2066, 2460. This grandfather provision applies both to the original Paragraph IV ANDA and to any subsequent Paragraph IV ANDA for the same listed drug.

treat Alzheimer's disease. (A100; A102; A104.) The '321, '864 and '911 patents were later patents to various "polymorph" (crystalline) forms of donepezil. (A497; A548-50; A552; A577-79; A602-04.) The '760 patent was a later patent directed to a formulation including donepezil. (A605-08.)

The '841 patent expires on Nov. 25, 2010. (A104.) Eisai disclaimed the '321 and '864 patents pursuant to 35 U.S.C. § 253 on May 22, 2006, and May 1, 2007, respectively. (A390; *see also* A35 ¶ 10.) The '911 patent expires on December 1, 2018, and the '760 patent expires on March 31, 2019. (A104.)

C. Procedural Background

1. Eisai's NDA for Aricept®

The FDA approved Eisai's NDA No. 20-690 for Aricept® (donepezil hydrochloride) on November 25, 1996. (A100, A102.) Because there was no other drug product in the United States containing the active ingredient, donepezil, the FDA awarded Eisai "new chemical entity" exclusivity. (A106.) Accordingly, the earliest date on which a generic drug company could file an ANDA containing a Paragraph IV Certification with respect to any of the patents listed by Eisai was November 25, 2000, four years after approval of the NDA. 21 C.F.R. § 314.108(b)(2). Generic drug companies therefore knew the precise day when they could become first-filers with respect to Aricept®.

2. Ranbaxy's ANDA and Teva's Two ANDAs

a. Ranbaxy's First-Filed ANDA

In August 2003, Ranbaxy Laboratories Ltd., a generic drug company, filed the first ANDA for generic donepezil with the FDA. (A108.) Ranbaxy made a Paragraph III Certification as to the '841 patent, respecting that patent and agreeing to wait to market a generic drug until that patent expires in November 2010. (A6.) Ranbaxy made Paragraph IV Certifications as to the DJ patents, stating its opinion that Ranbaxy's generic donepezil product did not infringe them. (A6-7; A109-111.) Ranbaxy thus became entitled to a 180-day market exclusivity upon final FDA approval of its application. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* A7.

Ranbaxy provided notice of its Paragraph IV Certifications, along with a statement of the factual and legal basis for its position of non-infringement, to Eisai on August 26, 2003. (A108-111.) In light of Ranbaxy's notice, Eisai did not sue Ranbaxy for infringement. (A7.)

b. Teva's First ANDA and Its Amendment

Teva had been following with "great interest" the development of Aricept® (asking Eisai for marketing rights in 1996), and had long known of the '841 patent **[confidential information deleted]**. (A113-14; A117.) **[confidential information deleted]** to market a generic donepezil product. (A124; A126 (noting **[confidential information deleted]**.)

[confidential information deleted]. (A128; A132 **[confidential information deleted]**.)

In October 2004, Teva filed its ANDA (No. 77-344) for generic donepezil. (A7; A136.) Like Ranbaxy, Teva made a Paragraph III Certification respecting the '841 patent, and a Paragraph IV Certification asserting noninfringement of the DJ patents. (A7; A136-37.) Teva acknowledged at the time of its application that **[confidential information deleted]**. (A134 **[confidential information deleted]**.) On December 7, 2004, Teva provided notice of this Paragraph IV Certification, along with a supporting statement, to Eisai. (A136-37.) In light of Teva's notice, Eisai did not sue Teva. (A7.)[3]

In July 2005, Teva requested a meeting with Eisai, during which it again asked for rights in Aricept®, this time threatening Eisai with a challenge to its '841 patent if Eisai refused. (A187-89.) After Eisai declined, in October 2005, Teva suddenly amended its ANDA to include a Paragraph IV Certification as to the '841 patent, claiming that donepezil had been obvious. (A7; A191-92.) Through this

3 In addition to Ranbaxy and Teva, as of the briefing below, twelve other generic drug manufacturers had filed ANDAs containing a Paragraph III Certification respecting the '841 patent and a Paragraph IV Certification as to the DJ patents. (A138-85; A495-96.) None was threatened or sued.

strategy, Teva became the first Paragraph IV filer (indeed, the only filer) with respect to the '841 patent, thereby allowing Teva to ***share*** first-filer status and the 180-day exclusivity period with Ranbaxy. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* A7. Teva noted at the time that **[confidential information deleted].** (A134 **[confidential information deleted]**.)

Upon receiving Teva's notice of the Paragraph IV Certification, in December 2005, Eisai sued Teva in the United States District Court for the District of New Jersey under 35 U.S.C. § 271(e)(2) for infringement of the '841 patent. (A7.) Eisai did not assert infringement of the DJ patents. (A7.) Because Eisai filed suit within 45 days, Teva's ANDA became subject to the 30-month stay of FDA approval. (A7.) The stay expired in April 2008, and the FDA gave final approval to Teva's ANDA on April 28, 2008. (A9; A279-82.)

c. Teva's Second ANDA and Its Amendment

In July 2005, Teva filed a second ANDA for a generic equivalent to Aricept®. (A7; A62; A119.) In November 2005, Teva re-filed this ANDA in the name of its unincorporated division, Gate Pharmaceuticals ("Gate"), under a new number, No. 78-000. (A83.)[4] Teva's second ANDA allegedly specified a different supplier of donepezil than Teva's first ANDA, although it was the same active

4 Teva and Gate share the same principal place of business and Teva does not dispute that Gate is the name of its unincorporated division that has no independent legal existence. (A7-8 & n.3.)

ingredient. (A8.) Even though Teva's first ANDA now contained Paragraph IV Certifications against all of the Eisai patents, Teva's second ANDA had no Paragraph IV Certifications and contained only Paragraph III Certifications. (A8.) Teva did not provide Eisai with notice that it had filed a second ANDA at that time.

In October 2007, approximately two years later, Teva amended its second ANDA to make Paragraph IV Certifications against all five listed patents, including the '841 patent. (A8; A201-02.) Upon receiving Teva's notice, Eisai filed another suit against Teva in the District of New Jersey for infringement of the '841 patent. (A8.) As with the prior lawsuit, Eisai did not sue Teva on the DJ patents.[5]

[5] Teva first disclosed the Paragraph IV Certification in its second ANDA during an October 2007 hearing in the '841 patent infringement suit, when Teva was seeking to amend its answer to add a defense of inequitable conduct. (A196-98.) Teva's notice concerning its second ANDA repeated the allegations of inequitable conduct Teva sought to add by amendment in the '841 patent litigation. (A215-21.) By amending the second ANDA in October 2007, Teva forced Eisai to file another suit for infringement of the '841 patent, which Teva expected to consolidate with the first suit, (A198), giving Teva an opportunity to plead the inequitable conduct defense irrespective of whether Teva could succeed on the motion to amend. There is no record evidence (or explanation other than litigation strategy) as to why Teva waited until October 2007 to first make a Paragraph IV Certification in its second ANDA.

At the time of the district court's ruling below, Teva's second ANDA had not received tentative approval from the FDA.[6]

3. Teva (Including Gate) Is Enjoined Under the '841 Patent

As discussed above, Eisai's actions against Teva alleged infringement only of the '841 patent. Initially, the only issue litigated in the first action was Teva's affirmative defense of obviousness set forth in its ANDA notice letter. (A8.) After litigating that defense for a year, in December 2006, Teva shifted and adopted an entirely new theory of obviousness. (A62 n.5); *see also Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, Civ. A. No. 05-5727, 2008 WL 1722098, at *1-2 (D.N.J. Mar. 28, 2008). In late 2007, Teva withdrew its obviousness defense entirely, conceding to the validity of the '841 patent and eliminating the original basis for the lawsuit. (A8-9); *Eisai*, 2008 WL 1722098, at *1. In April 2007, Teva admitted

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[6] The record contains no FDA correspondence or other documents showing when Teva's second ANDA will receive tentative approval, if at all before November 2010. Without tentative approval, an applicant cannot enter the market under an ANDA regardless of any patent-related issues. *See Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000). Teva submitted below a declaration by an employee who stated she was

[confidential information deleted] – thereby admitting that her declaration was without personal knowledge and hearsay – that Teva will have unspecified information

[confidential information deleted]. (A380 ¶¶ 7, 8.) Yet, at the time of the district court decision in September 2009 and even as of this briefing, Teva's second ANDA still lacks tentative approval.

that its generic drug would infringe various claims of the '841 patent. (A8.) In late 2007, Teva amended its answers to assert inequitable conduct, making that Teva's sole defense in the action. (A8-9.)

As noted above, the 30-month stay of approval of Teva's first ANDA expired in April 2008. (A9.) In December 2007, Teva disclosed to Eisai that it planned to launch "at-risk" generic donepezil upon receiving final FDA approval in April 2008, which would have devastated Eisai's business. (A9; A268-73.)

Eisai immediately sought a preliminary injunction. (A9.) Opposing Eisai's motion, Teva argued in support of the balance of hardships that it expected to make substantial profits on its planned sales of generic donepezil under its first ANDA, never suggesting that it was in any way dissatisfactory. (A64, citing *Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, Civ. No. 05-5727, Docket Entry No. 168, Leffler Decl. ¶¶ 9-10, 43, 46; (A609-14) and Docket Entry No. 163 at 5 (A615-17).) On March 28, 2008, the district court granted Eisai's motion and entered a preliminary injunction enjoining Teva (including its Gate division) from marketing any drug product containing donepezil until the expiration of the '841 patent. (A9.) This preliminary injunction remains in place. (A9.) In granting the injunction, the district court found that Teva's inequitable conduct defense lacked any substantial merit. *Eisai*, 2008 WL 1722098, at *9.

Teva did not appeal the district court's grant of the preliminary injunction.

4. Teva's Declaratory Judgment Action

On May 13, 2008, two months after being enjoined – and almost ***four years*** after first making Paragraph IV Certifications on the DJ patents – Teva surprised Eisai and filed the instant declaratory judgment action challenging the four DJ patents. (A9-10.) For the Court's convenience, a timeline of pertinent events appears in the Joint Appendix at A421.

In its initial complaint, Teva alleged that it faced a restraint on its ability to market generic donepezil commercially under both ANDAs because of the potential risk of future suit on the non-disclaimed DJ patents. (A36-37 ¶ 16.) With respect to the two patents that Eisai had disclaimed and its second ANDA, Teva asserted that, because they "remain in the FDA Orange Book," Teva "will not be able to obtain final FDA approval of its ANDA." (A37 ¶ 17.)

On May 20, 2008, Eisai confirmed that the '864 and '321 patents "have been disclaimed" and provided Teva with a written covenant confirming expressly what had been apparent before, that Eisai would not assert the DJ patents against the products described in Teva's ANDAs. (A285-86.) On October 2, 2008, Eisai provided Teva with a reaffirmed covenant not to sue. (A288-92.) On October 3, 2008, Teva dismissed Counts V and VI of its complaint, which had been based on alleged harm due to a risk of future suit. (A28 (Docket Entry. No. 15); A88.)

Three days later, Teva filed an Amended Complaint. (A29 (Docket Entry No. 17); A81-87.) The Amended Complaint deleted any allegations of commercial restraint based on potential risk of future lawsuit, and raised only one jurisdictional allegation, namely Teva's inability to secure immediate FDA approval for its second ANDA:

> Even 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.

(A84 ¶ 14.)

Eisai moved to dismiss for lack of subject matter jurisdiction. (A29 (Docket Entry No. 20).) On September 9, 2009, the district court granted Eisai's motion. (A1, A25.)

D. The District Court's Opinion

At the outset, the district court observed that, because Eisai has disclaimed two of the DJ patents and entered into a binding covenant not to sue on the other two patents, Eisai had no legal right to enforce the DJ patents against Teva. (A14-15.) Teva faced no restraint on its ability to market generic donepezil based on the possibility that Eisai may bring suit on the DJ patents. (A15.) The district court

then considered Teva's contention that Teva's second ANDA could not obtain immediate FDA approval and whether this alleged "injury ha[d] sufficient immediacy and reality to justify declaratory judgment jurisdiction." (A16-17.)

In addressing this question, the district court examined at length this Court's recent precedents on subject matter jurisdiction and the Hatch-Waxman Act: *Caraco Pharmaceutical 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). (A17-20.) In *Caraco*, this Court held that a later-filer had demonstrated on the facts of that case that declaratory judgment jurisdiction existed with respect to patents subject to a covenant not to sue. (A17-18 (citing *Caraco*, 527 F.3d at 1292-96).) On the facts of that case, this Court found jurisdiction because a favorable declaratory judgment would have cleared the path to FDA approval, permitting the first-filer early entry into the market while preserving its 180-day exclusivity, thereby allowing the second-filer into the market 181 days thereafter. (A18 (citing *Caraco*, 527 F.3d at 1293).)

In *Janssen*, this Court declined to find jurisdiction where the subsequent Paragraph IV ANDA filer, in addition to facing the same limitations on entering the market as the subsequent filer in *Caraco*, had also stipulated to the validity, infringement and enforceability of one of the patents against which it had filed a Paragraph IV Certification. (A19 (citing *Janssen*, 540 F.3d at 1361).) Therefore,

even if the subsequent filer won the declaratory judgment, it could not at that time enter the market. (A19-20 (citing *Janssen*, 540 F.3d at 1361).) Also, a desire to trigger the exclusivity of the first-filer at a time when that first-filer could not enter the market was not an injury cognizable under the Constitution; instead, the second-filer's need to wait until 181 days after the first-filer markets was the intended operation of the Hatch-Waxman Act. (A20 (citing *Janssen*, 540 F.3d at 1361).)

The district court carefully considered the facts of this case and concluded that it was akin to *Janssen*. (A19-22.) As the district court explained, Ranbaxy's exclusivity period was not the barrier to present market entry by Teva. (A20.) Teva itself shared a 180-day exclusivity period with Ranbaxy based on its own first ANDA. (A21.) And, irrespective of the DJ patents, Teva could not market donepezil before expiration of the '841 patent because it was enjoined under that patent. (A21.) The preliminary injunction "present[ed] 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." (A21-22.)

Teva's situation resembled that of the subsequent filer in *Janssen*, where the subsequent filer could not at the time of dismissal launch its generic product until the expiration of the active ingredient patent. (A22.) As in *Janssen*, Teva was

seeking to trigger the 180-day exclusivity period at a time when the first-filers (primarily Ranbaxy) could not market generic donepezil. (A22.) The district court concluded, "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*." (A22 (emphasis added).)

Because one could only "speculate . . . as to whether the preliminary injunction [against Teva] 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 here lack[ed] the sufficient immediacy and reality to establish declaratory judgment jurisdiction." (A23.)

In addition, the district court concluded that, even if Teva could satisfy the subject matter jurisdictional requirements, the court "would exercise its broad discretion pursuant to the Declaratory Judgment Act to decline jurisdiction." (A24.) The district court was well aware of "the particular circumstances of this case, including the multiple ANDAs and the relationship between Teva and Gate," and found that declining jurisdiction "would be consistent with the purposes of the Declaratory Judgment Act and properly conserve judicial resources." (A24.)

SUMMARY OF THE ARGUMENT

A federal court may exercise jurisdiction pursuant to Article III of the Constitution over a definite, concrete, and immediate controversy between parties with adverse legal interests that can be resolved conclusively by judgment. At all stages of the litigation, plaintiffs must demonstrate actual injury traceable to the defendant and redressable by the judgment.

No Article III controversy exists between Eisai and Teva with respect to the four DJ patents. Eisai has never threatened Teva or anyone with enforcement of any of them, has statutorily disclaimed two of them, and gave Teva an express covenant not to sue on the other two when asked. Teva attempts to manufacture a controversy with Eisai by claiming that the DJ patents are blocking Teva's ability to market a generic donepezil product under Teva's second ANDA. But the DJ patents do not bar Teva's market entry. Teva is a first-filer with FDA approval to market generic donepezil, and Teva would be able to market that product today were it not for the injunction the district court issued under the '841 patent preventing Teva from marketing any generic donepezil product which infringes that patent.

Nor is there merit to Teva's claim that the DJ patents may eventually affect its ability to market product under its second ANDA (filed in the name of Teva's Gate division). Teva insists that *if* the district court reaches final judgment in the

injunction action before the '841 patent expires and *if* the district court rules in Teva's favor on its inequitable-conduct defense (after having found the defense lacking in substantial merit), and *if* Ranbaxy does not thereupon market generic donepezil under its first ANDA commercially, then a declaratory judgment that Teva's second Gate product does not infringe each of the four DJ patents would be needed to trigger Ranbaxy's 180-day period of exclusivity (which, Teva claims, in turn would affect the time at which Teva can bring its second product to market).

Teva's attenuated and contingent chain of causation is laden with factual inaccuracies, and would not satisfy Article III's requirement of a definite and immediate controversy even if correct. First, Gate is merely an unincorporated division of Teva, as the district court ruled, and not a distinct legal entity. If the '841 patent were no longer a barrier, Teva (without any declaratory judgment on the DJ patents) may obtain final approval from the FDA of its second ANDA by marketing generic donepezil under its first ANDA, triggering the 180-day exclusivity, and selectively waiving the exclusivity in favor of Teva's second ANDA. Second, Teva has only itself to blame for having the product of its second ANDA subject to regulatory exclusivities of earlier-filed ANDAs. Teva chose to file Paragraph IV Certifications in two ANDAs at different times. If Teva timed them together, they would have shared the 180-day exclusivity period along with Ranbaxy's ANDA, and Teva's first and second ANDAs could have been eligible

for final FDA approval at the same time. Teva also could have amended its first ANDA to add the supplier identified in its second ANDA. A plaintiff cannot establish Article III jurisdiction by alleging a self-inflicted injury from its own voluntary business decisions. At the very least, Teva's alleged injury is not attributable to an act of Eisai with regard to the DJ patents. Teva has failed to satisfy the requirements of Article III jurisdiction.

Even if Teva's chain of events were theoretically possible, the mere possibility of future and contingent injury does not give rise to Article III jurisdiction. Teva's exclusion from the market under either ANDA has nothing to do with the DJ patents: Teva is enjoined under the '841 patent claiming the active ingredient donepezil. The district court properly found that Teva failed to allege a controversy of sufficient immediacy to support federal jurisdiction.

Teva is wrong in asserting that an injunction is no different from the 30-month stay of FDA approval which would have applied to Caraco. The 30-month stay is an automatic and necessarily temporary procedure, arising simply on the patentee's filing of an infringement action. The district court here enjoined Teva based on the substantive and express finding that Teva's sole defense of inequitable conduct lacks substantial merit. The district court so concluded even though, at the preliminary injunction phase, Eisai bore the burden of proof; at trial, Teva would bear the burden of proving inequitable conduct by clear-and-

convincing evidence. Teva's arguments about defeating the injunction are remote and speculative, to say the least.

In a desperate attempt to manufacture jurisdiction, Teva cites extra-evidence and argues for the first time on appeal that the DJ patents may become relevant if Ranbaxy is unable to bring a generic product to market. Not only is this procedurally impermissible, and legally insufficient speculation, but it is also unavailing – the extra-record evidence does not in fact suggest Ranbaxy will be delayed in introducing generic donepezil.

Also, unlike *Caraco*, Teva is seeking a declaratory judgment that its products do not infringe *disclaimed* patents. Eisai is in no sense adverse to Teva with regard to these patents. Teva claims only that it is being injured because the FDA is still listing them. Teva never sought to have the FDA delist them. And, Teva was among the generic manufacturers that successfully obtained a judgment forcing the FDA to adopt this policy. At best, Teva's complaint is with the FDA about an alleged injury of its own making, not a patent infringement dispute with Eisai.

Finally, even if an Article III controversy did exist, the district court did not abuse its discretion by (in the alternative) declining to entertain this action. The Hatch-Waxman's Act use of the standard language that district courts "shall have jurisdiction" does not extinguish the district court's traditional discretion to deny

declaratory relief if it does have jurisdiction. As can be seen from the facts above, this case presents unusual circumstances: Teva fabricated a patent challenge in its first ANDA to become a first-filer and obtain shared 180-day exclusivity, belatedly then filed a Paragraph IV Certification in a second ANDA subjecting it to the exclusivity of Teva's own first ANDA, obtained final FDA approval of its first ANDA and then was enjoined from selling generic product under both ANDAs, and then brought a DJ action four years after first making its Paragraph IV Certification and not having being sued on those patents, all with respect to patents that are either disclaimed or subject to a covenant not to sue. As can be imagined, the district court's scarce resources are better devoted toward resolving real problems between adverse parties.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews a district court's dismissal of a declaratory judgment action for lack of jurisdiction *de novo*. *Janssen*, 540 F.3d at 1359. To the extent there are any jurisdictional facts in dispute, they are reviewed for clear error. *Can. Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1330-31 (Fed. Cir. 2008).

The party claiming declaratory judgment jurisdiction, here Teva, had the burden of proof that such jurisdiction existed at the time its complaint was filed

and at all stages of review. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007); *Janssen*, 540 F.3d at 1360.

II. NO ARTICLE III CONTROVERSY EXISTS BETWEEN THE PARTIES

A. Teva Has Not Proven a Definite, Concrete, And Immediate Controversy Between Adverse Parties That Can Be Resolved Conclusively By Judgment

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). The Hatch-Waxman Act authorizes ANDA filers to commence declaratory judgment actions, to the extent permitted by the Constitution, to obtain "patent certainty" if not sued for infringement by the patentee. *See* 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5); *Caraco*, 527 F.3d at 1285. As discussed above (pages 14-15), Teva withdrew the allegations in its first complaint regarding patent uncertainty. Teva's declaratory-judgment action does not otherwise satisfy the requisites of Article III of the Constitution.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon v. E. Ky. Welf. Rights. Org.*,

426 U.S. 26, 37 (1976). To be within the jurisdiction of the federal courts, Article III "require[s] 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 admit of specific relief through a decree of a conclusive character." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-241 (1937)) (internal quotations omitted) (emphasis added). The existence of a case or controversy cannot be established by conjectural or insubstantial allegations, and the district court must make a context-specific determination based on the entirety of the circumstances presented.

Thus, when a plaintiff seeks a declaratory judgment in a patent case, Article III jurisdiction turns on "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." *MedImmune*, 549 U.S. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co*., 312 U.S. 270, 273 (1941)) (internal quotations omitted) (emphasis added).

There is no Article III controversy if the plaintiff lacks standing to seek redress against the defendant. The "irreducible constitutional minimum of standing" consists of three elements:

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact" – a harm suffered by the plaintiff that is "concrete" and "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability – a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03 (1998) (internal citations omitted).

Here, Teva has failed to allege an Article III controversy. Teva has suffered no actual or imminent injury at Eisai's hands due to the DJ patents. Two of the four DJ patents (the '864 and '321 patents) were disclaimed before Teva even filed its Paragraph IV Certification in the second ANDA. There is no controversy between Teva and Eisai over disclaimed patents that are nullities in the eyes of the law, and which no longer reflect property rights in Eisai. *E.g.*, *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935); *Guinn v. Kopf,* 96 F.3d 1419, 1422 (Fed. Cir. 1996); *White Mule Co. v. ATC Leasing Co.*, 540 F. Supp. 2d 869, 881 (N.D. Ohio 2008) (the patentee's formal disclaimer "leaves [the court] with no 'actual controversy' to adjudicate").

Eisai has granted Teva a covenant not to sue on the other two DJ patents (the '911 and '760 patents), and there is no actual controversy between the parties as to those patents. Equally unavailing is the assertion that Eisai's actions with regard to

the DJ patents are blocking Teva from bringing generic donepezil to market. Indeed, Teva's delay of *four years* to file its declaratory judgment action casts doubt on the credibility of the assertion of harm. Teva is blocked from bringing generic donepezil to market because the district court enjoined Teva from doing so under a separate Eisai patent not involved in this suit. The district court based its injunction on a finding that Teva's last-resort inequitable conduct defense lacked any substantial merit. To the extent Teva is delayed in marketing a generic donepezil using a second supplier, named in Teva's second ANDA, that is simply a function of the operation of the Hatch-Waxman Act, Teva's voluntary business decisions, and its ill-conceived strategy to launch an attack on its competitor Ranbaxy through this litigation. Allegations of self-inflicted injury do not give rise to Article III jurisdiction.

B. *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.* Does Not Support Article III Jurisdiction In The Circumstances Presented Here

Teva stakes its entire claim to Article III jurisdiction on an argument that this Court's decision in *Caraco* "requires" reversal. (Teva Br. at 14-15.) Teva's reliance on *Caraco* is misplaced, and glosses over the different factual circumstances of *Caraco*.

In *Caraco*, the generic manufacturer Ivax Pharmaceuticals was the first to file Paragraph IV challenges on all of the Orange Book patents listed for the drug,

and thus enjoyed the 180-day exclusivity period. 527 F.3d at 1286. The patentee (Forest Laboratories) successfully enjoined Ivax from market entry under the '712 active-ingredient patent, which did not expire until 2012. *Id.* "By holding the '941 patent in reserve, Forest insulated itself from an invalidity or noninfringement challenge by Ivax." *Id.* Forest was found to be blocking not only Ivax but also other subsequent ANDA filers from the market "indefinitely." *Id.* at 1292.

The declaratory judgment plaintiff, Caraco Pharmaceutical Laboratories, was the second-filer on all the Orange Book patents, like the first-filer. *Id.* at 1288. Caraco brought a declaratory judgment action on the second Orange Book patent. *Id.* The patentee moved to dismiss, and subsequently provided a covenant not to sue. *Id.* at 1288-89.

The *Caraco* Court explored the broad "all-the-circumstances" test under *MedImmune*. *Id.* at 1290-91. It recognized that the covenant not to sue eliminated a reasonable apprehension of suit by the defendant, but held that this fact, though relevant, was not dispositive under *MedImmune*. *Id.* at 1291, 1294 n.13. The Court found under the totality of the circumstances that Caraco had standing and had asserted an Article III case or controversy against Forest. The Court found that Caraco was injured because it was "exclu[ded] from the generic drug market" by the patents in the declaratory judgment action. *Id.* at 1291-92. The Court next found that the patentee's conduct caused Caraco's injury because the patentee's

listing of the declaratory judgment action patent, and enforcement of the other Orange Book patent against the first-filer (Ivax), "effectively denie[d] Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both [Orange Book] patents are invalid or not infringed by its generic drug." *Id.* at 1292-93. The Court found that Caraco's injury was redressable because a "favorable judgment in this case would clear the path to FDA approval." *Id.* at 1293.

Finally, the Court found that if Caraco succeeded, "this would trigger Ivax's 180-day exclusivity period ***at a time when Ivax could obtain FDA approval and then launch its product***." *Janssen*, 540 F.3d at 1361 (discussing *Caraco*) (emphasis in original); *see Caraco*, 520 F.3d at 1287. Caraco would thus be permitted market entry 181 days thereafter. This was sufficient for the Court to find the existence of an Article III controversy.

The factual circumstances here contrast sharply with those described in *Caraco* in at least five material respects:

(1) Teva is a first-filer and already has FDA approval to sell generic donepezil, *unlike Caraco*;

(2) Teva's second ANDA is subject to the 180-day exclusivity of its own first ANDA as a known result of Teva's voluntary actions, *unlike Caraco's*;

(3) Teva is enjoined under the basic compound patent, *unlike Caraco*;

(4) the first-filer Ranbaxy (like multiple generic drug companies and, originally, Teva itself) has filed a Paragraph III Certification respecting the basic compound patent, *unlike Ivax*; and

(5) two of the DJ patents are disclaimed.

The circumstances of this case reveal that Teva alleges an injury that is illusory, speculative, not caused by any action of Eisai with respect to the DJ patents, and not redressable by declaratory judgment. The district court correctly determined that Teva failed to prove Article III jurisdiction in these circumstances.

C. Teva Failed To Prove Injury Caused By Eisai

1. The DJ Patents Do Not Delay Teva's Entry Into The Generic Market

Unlike Caraco, Teva is itself a first-filer with FDA approval to market generic donepezil. The DJ patents are not a barrier to Teva's market entry; the barrier to its market entry is an injunction under the '841 patent, which is not redressable in Teva's declaratory judgment action.

Teva asks this Court to disregard its status as a Paragraph IV ANDA first-filer, and to pay heed only to its second ANDA (nominally filed by its Gate Pharmaceutical division). "Gate is merely an unincorporated division of Teva, and appears to have no legal status independent of Teva." (A20-21.) As the district court correctly stated:

> 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."

Id. (citing *Caraco*, 527 F.3d at 1296).

Teva does not contest the district court's finding that "Gate" is just the name of its unincorporated division with no independent legal standing. *See, e.g., Transocean Gulf Oil Co. v. Parapada Shipping Co.*, 547 F. Supp. 93, 94 (D. Del. 1982) (a mere unincorporated division has no legal existence and no independent standing to sue); *Affymax, Inc. v. Johnson & Johnson*, 420 F. Supp. 2d 876, 879 (N.D. Ill. 2006) (same).

Even though Teva is not excluded from the generic donepezil market, Teva maintains that its status as a Paragraph IV first-filer will not enable it to sell the particular generic product covered by its second ANDA. (Teva Br. at 38.) Teva ignores that it can market generic donepezil under its first ANDA, triggering the 180-day exclusivity, and selectively waive the exclusivity in favor of Teva's second ANDA. (A463 n.3; A464-65 ("FDA has consistently interpreted [21 U.S.C. § 355](j)(5)(B)(iv) . . . to permit both waiver and relinquishment of 180-day exclusivity benefits.").) Teva has used selective waiver in the past to gain immediate FDA approval of an ANDA otherwise subject to a 180-day exclusivity.

(A477 (Letter from FDA to Teva granting final FDA approval); A482-84.) Teva also could have amended its first ANDA to add the supplier named in its second ANDA. The DJ patents do not stand in the way of Teva's marketing a generic version of Aricept®.

2. Teva's Alleged Injury Is Of Its Own Making, And Is Not Attributable To Eisai

It would not suffice for Teva to allege "the bare existence of an abstract injury"; it must show a "direct relationship between the alleged injury and the claim sought to be adjudicated." *Linda R. S. v. Richard D.*, 410 U.S. 614, 618 (1973) (internal quotation marks omitted). Here, any "injury" that Teva allegedly suffers from the fact that its Gate product is not covered by its first ANDA and that its second ANDA is subject to the 180-day exclusivity of its first ANDA is attributable to Teva's knowing voluntary business decisions, not due to any conduct by Eisai. In fact, Eisai did not even learn of the existence of the Paragraph IV filing in Teva's second ANDA until October 2007, after Eisai had disclaimed two of the DJ patents, and two years after it had sued Teva for infringement of the '841 patent (but not the DJ patents) based on Teva's first ANDA.

Teva elected to delay five years (from November 2000 until October 2005) to file a Paragraph IV Certification as to the '841 patent in its first ANDA, and then to wait two more years, until October 2007, to file a Paragraph IV

Certification in Teva's second ANDA. Teva knew that its course of conduct would mean that its second ANDA was subject to the 180-day exclusivity of Teva's first-filed ANDA (and Ranbaxy's ANDA), which is precisely how the Hatch-Waxman Act was intended to operate.

If Teva had arranged to file Paragraph IV Certifications in both its ANDAs at the same time, then Teva's second ANDA in the name of Gate would have shared exclusivity with its first ANDA and with Ranbaxy's ANDA, and Teva could have sought final approval for both ANDAs, just as it now has final approval for the first ANDA. *See* FDA Guidance, 68 Fed. Reg. 45252-01, 2003 WL 21766146 (Fed. Reg. Aug. 1, 2003) (under the Hatch-Waxman Act, if two Paragraph IV Certifications were filed the same day, the ANDAs would share exclusivity).

"A plaintiff cannot establish Article III standing to pursue a cause of action where that plaintiff is the primary cause of its own alleged injury." *Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc.*, 454 F. Supp. 2d 62, 71 (E.D.N.Y. 2006); *Taylor v. FDIC*, 132 F.3d 753, 767 (D.C. Cir. 1997); *Bhd. of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006); *see also Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (no jurisdiction where plaintiff's alleged injury was "self-inflicted").

D. A Separate Injunction Prohibits Teva from Marketing Generic Donepezil, And Any Alleged Market Exclusion Injury Is Not Caused By The DJ Patents Or Redressable By Declaratory Judgment

Even apart from Teva's voluntary actions, there is no Article III controversy if the injury has an independent and sufficient cause that will not be eliminated by resolution of the case. *Simon*, 426 U.S. at 41-42; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Here, there is an independent barrier to Teva's ability to market generic donepezil (under either its first or second ANDA), namely, the injunction entered by the district court in the '841 patent infringement action, which states:

> Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., and Gate Pharmaceuticals . . . and those acting in privity or concert with them . . . are restrained and enjoined from engaging in the commercial manufacture, use, offer to sell or sale within the United States . . . of any drug product containing donepezil or a pharmaceutical acceptable salt thereof, as claimed in United States Patent No. 4,895,841.

Eisai, 2008 WL 1722098, at *13.

As the district court correctly held, the injunction and its consequences distinguish this case from *Caraco*, making it more akin to *Janssen*. (A22.)

In *Janssen*, Teva owned the 180-day exclusivity as the first-filer of an ANDA containing Paragraph IV Certifications to every patent covering the drug at issue, except the basic compound patent (the '663 patent). 540 F.3d at 1358. Like

Ranbaxy here, Teva had filed a Paragraph III Certification as to the basic compound patent.

A second generic manufacturer, Mylan, had tried to attack the basic compound patent, but the patent was found valid and infringed. *Id.* Apotex, another generic manufacturer, subsequently filed Paragraph IV Certifications as to all the patents covering the drug, but was sued by Janssen on just the basic compound patent. Apotex immediately brought a declaratory judgment action as to the remaining patents, and received a covenant not to sue. *Id.* Apotex agreed to be bound by the judgment in the Mylan action and therefore was blocked by the basic compound patent from entering the market. *Id.*

Apotex claimed that the district court had jurisdiction over the declaratory judgment action on the ground that Apotex, as a later filer, was being harmed because it could not get FDA approval and market its generic drug until after Teva's statutory 180-day exclusivity had expired. *Id.* at 1359-60. Apotex wanted to obtain a declaratory judgment to trigger Teva's 180-day exclusivity, at a time when Teva could not market its drug due to its Paragraph III Certification on the basic compound patent. If successful, Apotex would have been able to enter the market immediately upon expiration of the basic compound patent. *Id.* at 1360.

This Court in *Janssen* rejected jurisdiction, finding that Apotex's "inability to launch its generic product immediately upon the expiration of the [basic

compound patent] is not sufficient to give rise to declaratory judgment jurisdiction." *Id.* at 1360. Unlike the plaintiff in *Caraco*, Apotex "cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent." *Id.* at 1361. This Court found that a later-filer's "inability to promptly launch its generic [drug] product because of [a first-filer's] 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." *Id.*; *see also id.* at 1362 (reiterating that a later-filing generic manufacturer's "exclusion from the market because of [the first-filer's] entitlement to this [180-day] statutory exclusionary period does not present a justiciable Article III controversy").

As the district court reasoned, *Janssen* is persuasive in finding no Article III controversy between Teva and Eisai:

> [T]he 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.

(A22.)

Teva attempts to refute the district court's analysis, but to no avail. It claims that the '841 patent injunction cannot be analogized to the concession of patent validity in *Janssen* because the district court here has not yet entered a permanent injunction. (Teva Br. at 14-15.) Teva further argues that the injunction provides no distinction from *Caraco*, because Caraco was subject to the remainder of the automatic 30-month stay of FDA approval provided in 21 U.S.C. § 355(j)(5)(B)(iii). (Teva Br. at 14-15, 33-35.)

Teva is wrong. A fundamental difference is that the statutory 30-month stay is an automatic and necessarily temporary procedure; it arises simply on the patentee's filing of an infringement action against the Paragraph IV filer. *See* 21 U.S.C. § 355(j)(5)(B)(iii). By contrast, the district court here granted the preliminary injunction to Eisai based on Teva's concession of infringement of the '841 patent, concession of patent validity, and an express finding that Teva's sole remaining inequitable-conduct defense "lacks substantial merit." *Eisai*, 2008 WL 1722098, at *9. Teva did not appeal from that ruling. The injunction will not lapse on its own accord prior to expiration of the '841 patent.

Teva's inequitable-conduct defense was a last-resort allegation, asserted only after Teva changed and then voluntarily withdrew a sham obviousness defense which Teva had made to obtain shared 180-day exclusivity and leverage such exclusivity against Eisai through the threat of final FDA approval and launch of generic donepezil product. (*See supra*, at 8-10, 12-13.) The defense of inequitable conduct requires clear and convincing proof that a person with the duty of candor failed to disclose material information to the PTO and had the specific intent to deceive or mislead the PTO. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 & n.5 (Fed. Cir. 2009).

Teva's theory of inequitable conduct was that Eisai failed to disclose a prior Eisai patent and a 1984 article (the Kenley article) discussing antidotes for warfare nerve-agents, which, in combination, purportedly would have caused a reasonable examiner to find double-patenting over '841 patent claims that were not even the claims specific to donepezil. *Eisai*, 2008 WL 1722098, at *8-9. The district court examined these assertions on the merits in detail, based on a voluminous record submission, including affidavit testimony of the author of the article itself. *Id.* at *9. The district court found that "Teva's argument about what a reasonable patent examiner would have concluded based upon the Kenley article requires the piling of inference on inference, a hermeneutical act specifically proscribed by the Federal Circuit." *Id.* at *9 (citing *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411,

1417 (Fed. Cir. 1987)). The district court concluded that there was no "substantial likelihood that a reasonable examiner would have considered the Kenley article important in deciding whether to allow the application to issue as a patent." *Id.*

The court concluded that "Teva's inequitable conduct defense lacks substantial merit inasmuch as Teva is not likely to succeed at trial in demonstrating materiality *or* intent," and issued the preliminary injunction. *Id.* (emphasis added). Despite its current protestations, Teva did not appeal the district court's injunction.

This is in stark contrast to an automatic and temporary regulatory stay of FDA approval. The injunction is an independent and substantive barrier to Teva's market entry, both as to its first and second products; the DJ patents are not responsible for Teva's exclusion. *See Comsat Corp. v. F.C.C.*, 250 F.3d 931, 936 (5th Cir. 2001) (finding no injury in fact where "there are various FCC regulations, unrelated to the challenged rule, that prevent Comsat from expanding its interstate services").

Teva relies (Teva Br. at 24) on the bare theoretical possibility that the district court could change its findings on both materiality and intent and find inequitable conduct on the merits (even though it was Eisai that bore the burden of proof at the preliminary injunction phase, whereas Teva will bear the burden of proof of proving inequitable conduct by clear-and-convincing evidence at the permanent injunction phase, *see Eisai*, 2008 WL 1722098, at *3). But to allege an

Article III controversy, a plaintiff cannot simply assert "the remote possibility, unsubstantiated by allegations of fact, that their situation . . . might improve were the court to afford relief." *Warth v. Seldin*, 422 U.S. 490, 507 (1975). A plaintiff must show the "*substantial likelihood* that the requested relief will remedy the alleged injury." *McConnell v. FEC*, 540 U.S. 93, 225-26 (2003) (emphasis added), *overruled on other grounds*, *Citizens United v. FEC*, -- U.S. --, 2010 WL 183856 (Jan. 21, 2010).

Teva did not set forth allegations establishing a substantial likelihood that the DJ patents will cause it harm, and that this action will likely redress that harm. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) ("A threatened injury must be certainly impending to constitute injury in fact."). As the district court stated, Teva is simply "speculat[ing] 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." (A23.) Teva had the burden of showing that declaratory judgment jurisdiction existed at the time of filing and at all stages of review. *Janssen*, 540 F.3d at 1360. Teva failed to carry that burden. The district court did not rule on whether Teva could assert a declaratory judgment claim if all the manifold contingencies in its attenuated chain of causation came to pass and lost their speculative quality. (A23.) *See Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1157 (10th Cir. 2005) ("The plaintiff's burden of demonstrating causation is

not satisfied when 'speculative inferences are necessary to connect [its] injury to the challenged actions.'") (quoting *Simon*, 426 U.S. at 45-46).

Indeed, if Teva could lift the injunction, permitting it to market donepezil, Teva would be able to selectively waive the exclusivity of its first ANDA in favor of its second ANDA, and market under its second ANDA. (*See supra*, at 31-32.) Thus, even in that speculative future situation, Teva is not blocked by the DJ patents.

In any event, the district court rightly found that "jurisdiction is wanting at this time," for "the potential injury alleged by Teva here lacks the sufficient immediacy and reality required to establish declaratory judgment jurisdiction." (A23.)

E. Teva's New Extra-Record Arguments About Indefinite Delay by Ranbaxy Do Not Make Its Appeal Meritorious

Having lost below on a record that demonstrates that the DJ patents are not injuring Teva, that Eisai is not the cause of Teva's alleged injury, and that a declaratory judgment will not redress Teva's alleged injuries, Teva shifts positions yet again and cites snippets of evidence outside the record on appeal in a desperate attempt to mislead this Court.

Teva argues that, because the FDA suspended drug approvals associated with two facilities in India, Ranbaxy may not be able to enter the market after

expiration of the '841 patent later this year. (Teva Br. at 9-10, 40.) Teva's chief "evidence" is a February 2009 FDA press release that Teva could have submitted (but did not submit) to the district court prior to the issuance of final judgment in September 2009. (*Id.* at 9-10.) Teva's reliance on extra-record evidence and new argument on appeal unquestionably is improper. *See Ballard Med. Prods. v. Wright*, 821 F.2d 642, 643 (Fed. Cir. 1987) ("An appellate court may consider only the record as it was made before the district court."); *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 1550 (Fed. Cir. 1987).

But even if this Court were to countenance extra-record evidence on this point,[7] Teva fails to disclose that donepezil was ***not*** one of the drugs the FDA identified as being manufactured at these Ranbaxy facilities. *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118441.htm. Even as to other drugs made at those facilities, Ranbaxy has ***still*** been able to market them by using different facilities.[8] Finally, there is no

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[7] Eisai refers in this paragraph to extra-record evidence out of an abundance of caution in the event Teva's submission were to be considered, to prevent the Court from being misled.

[8] *E.g., Ranbaxy Launches Generic Valtrex in the US, Shares Rise*, Dow Jones DE, Nov. 27, 2009, available at http://www.dowjones.de/site/2009/11/ranbaxy-launches-generic-valtrex-in-us-shares-rise.html; *Daiichi to Leverage Ranbaxy Abroad*, Economic Times, Nov. 11, 2009 (discussing switch of drug production to other facilities), available at http://economictimes.indiatimes.com/articleshow/5217703.cms.

evidence that Ranbaxy will not resolve the issues with the two facilities by November 2010 when the '841 patent expires. Thus, even if donepezil's production occurred at the two facilities – and there is no evidence that it does – and even if Ranbaxy continued having problems with those facilities in November 2010 – and there is no evidence it will – Teva still does not show any reason why Ranbaxy could not sell generic donepezil using another facility as it is doing with other products.

Also, with or without the extra-record evidence, Teva's argument suffers from legal error: "[A] possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction." *Janssen*, 540 F.3d at 1363. Teva should know of this holding from *Janssen* because the Court was referring to Teva, who was then the first-filer.

Teva makes wild accusations that Eisai is holding the DJ patents in reserve so as to sue Ranbaxy upon its launch in 2010 and obtain an emergency injunction – seven years after being notified of Ranbaxy's plans to do so. (Teva Br. at 40.) This unfounded argument was not raised below and is not part of Teva's jurisdictional allegations. The argument does not even make sense because two of the DJ patents are disclaimed. That Ranbaxy did not bring a declaratory judgment action confirms Teva's argument has no substance.

F. Teva Failed To Prove An Article III Controversy As To The Disclaimed Patents

Another critical distinction from *Caraco* is that Eisai has disclaimed two of the patents for which Teva is seeking a declaratory judgment of non-infringement.

A disclaimer operates as "part of the original patent." 35 U.S.C. § 253. "A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent." *Guinn*, 96 F.3d at 1422; *Altoona Publix Theatres*, 294 U.S. at 492 ("Upon the filing of the disclaimers, the original claims were withdrawn from the protection of the patent laws, and the public was entitled to manufacture and use the device originally claimed as freely as though it had been abandoned.").

Eisai thus has no property rights in disclaimed patents. *See Underwood v. Gerber*, 149 U.S. 224, 231 (1893). Eisai holds no adverse legal interest with respect to Teva based on the '321 and '864 patents, and this presents an independent ground for dismissal as to those patents.

Courts universally have held that they lack subject matter jurisdiction to issue substantive rulings about infringement *vel non* of disclaimed patents. *Merck & Co. v. Apotex, Inc.*, Civ. A. No. 06-5789, 2007 WL 4082616, at *5 (D.N.J. Nov. 15, 2007) ("Thus, because Merck has formally disclaimed the '735 and '443 patents, and can no longer enforce any claims as to these patents, there is

no justiciable case or controversy to support jurisdiction in an action for a declaratory judgment here."); *Belk, Inc. v. Meyer Corp.*, Civ. A. No. 07-168, 2008 WL 2704792, at *3-4 (W.D.N.C. July 7, 2008) (dismissing declaratory judgment claim as to a disclaimed patent); *W.L. Gore & Assocs., Inc. v. Oak Materials Group, Inc.*, 424 F. Supp. 700, 702 (D. Del. 1976) ("As plaintiff has formally disclaimed all claims of the patent, there is no longer a justiciable case or controversy before the Court with respect to the validity of any of those claims."); *White Mule*, 540 F. Supp. 2d at 881 (the patentee's formal disclaimer "leaves [the court] with no 'actual controversy' to adjudicate"); *Technimark, Inc. v. Crellin, Inc.*, 14 F. Supp. 2d 762, 763, 766-67 (M.D.N.C. 1998) (holding that dedication of the patent under § 253 rendered moot counterclaims of patent noninfringement and invalidity); *Jack Winter, Inc. v. Koratron Co.*, 327 F. Supp. 206, 211-212 (N.D. Cal. 1971) ("The arguments of [the declaratory judgment plaintiff] going to invalidity of the '915 patent . . . cannot be determined because they are not live controversies."); *see also Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 525 F. Supp. 2d 680, 686 (D. Del. 2007) ("The existence of issued and presently enforceable patent claims against a declaratory judgment plaintiff is a necessary prerequisite to the continued litigation of a declaratory judgment action.").

Eisai disclaimed the '321 and '864 patents on May 22, 2006, and May 1, 2007, respectively, over a year before Teva commenced this declaratory judgment

action on May 13, 2008. (A9-10; A390.) Despite multiple ANDAs filed by Teva over several years, Eisai had never sued Teva on the disclaimed patents (or indeed any of the DJ patents). Eisai's inactivity is consistent with the fact that Eisai has never sued Ranbaxy or the other numerous generic manufacturers who have filed Paragraph IV Certifications against these patents. Teva does not cite a single case where a court assumed subject matter jurisdiction in order to issue substantive patent rulings about a disclaimed patent. Teva cannot show a dispute "touching the legal relations of [Eisai and Teva]" or that Eisai and Teva have "adverse legal interests." *MedImmune*, 549 U.S. at 127.

Teva's sole complaint with respect to the disclaimed patents is that the ***FDA*** is still listing them in the Orange Book, thereby resulting in Teva's second ANDA being subject to the 180-day exclusivity of Teva's and Ranbaxy's first ANDAs. (Teva Br. at 5, 29-30 & n.12.) But this complaint asserts at most adversity to the FDA's procedure, not a patent infringement dispute with Eisai.

Teva never alleges that it requested the FDA to delist the disclaimed DJ patents. Teva also fails to tell this Court that Teva itself was among the generic manufacturers who previously sued the FDA to *force* the FDA to continue listing patents if a Paragraph IV Certification had previously been filed, specifically to prevent any harm to the 180-day exclusivity period earned by the first-filer. *See Ranbaxy*, 469 F.3d at 121, 123-24 (adopting Teva's argument that it was critical to

the intended incentive system of the Hatch-Waxman Act for the FDA to leave the patents listed, in order to maintain the 180-day exclusivity of the first Paragraph IV filer). Teva and others forced the FDA to adopt the very procedure it now complains about at a time when it benefitted Teva as a first-filer. Teva argued that this was necessary to protect the 180-day exclusivity of the first-filer which was integral to the incentive structure of the Hatch-Waxman Act. *Id.* at 123-24, 126.

It would distort core principles of Article III jurisdiction if a district court were to undertake the surreal task of considering the legally non-existent claims in the disclaimed '864 and '321 patents, and then determining whether Teva's generic products would have infringed the construed claims if they still existed, when in fact the defendant Eisai has no legal interest in the patent. Certainly, Eisai has no incentive to commit the substantial resources entailed in patent litigation to submit Teva's claims to adversarial testing. Indeed, without adversarial legal interests, Teva would be asking the district court to issue prohibited advisory opinions based solely on Teva's arguments. *See Muskrat v. United States*, 219 U.S. 346, 357 (1911).

This Court should not find that district courts have Article III jurisdiction to rule on substantive issues concerning non-existent property rights because of Teva's complaint that the FDA is listing these patents to preserve the first-filer's earned 180-day exclusivity period – particularly when the FDA was forced to

adopt this very procedure because Teva convinced another Court that the procedure achieved a result envisioned by the Hatch-Waxman Act (at a time when Teva was a first-filer). *Ranbaxy,* 469 F.3d at 123, 126.

G. Teva Is Not Seeking To Redress Injury Caused By Eisai, But Rather To Burden Eisai With Unnecessary Litigation And Inflict Injury On Its Generic Competitor Ranbaxy

As the foregoing makes clear, this declaratory judgment action is not about seeking redress of an injury caused by Eisai. Rather, it is a vehicle for Teva to try to deprive its competitor Ranbaxy of the statutory exclusivity period to which Ranbaxy is entitled under the Hatch-Waxman Act, burdening the district court and Eisai in the process.

Teva claims that it matters not that the first-filer in *Caraco* had filed Paragraph IV Certifications as to all Orange Book Patents, whereas Ranbaxy here did not (filing instead a Paragraph III Certification to the '841 patent, which is the basic compound patent). (Teva Br. at 30 n.11.) That is wrong, and it goes to the heart of Teva's strategy.

Ranbaxy and the twelve subsequent ANDA filers (plus Teva in 2004, but not Teva in 2005 and 2007) acted properly and respected Eisai's valid patent on the active ingredient in a critically important drug for the treatment of Alzheimer's disease. Those companies recognize that they have no good-faith defense of either non-infringement or invalidity with regard to the '841 basic compound patent; each

has filed a Paragraph III Certification as to that patent and accepted that it has to await the expiration of the '841 patent to introduce generic versions of donepezil. Even Teva admits to the validity and infringement of that patent. (A8.)

Teva spins tales of possible gamesmanship by patentees who can lie in wait until the first patent expires and then pounce with an infringement action to further block generic entry, or sue a first-filer and not a second-filer. (Teva Br. at 20-22.) But that is not the situation here. Eisai sued Teva as both a first- and second-filer. Ranbaxy will be able to market generic donepezil this coming November, and the later-filers 181 days thereafter. If Ranbaxy believed Eisai was lying in wait, it would have brought a declaratory judgment action of its own for "patent certainty." Eisai did not sue any of the multiple Paragraph III Certification filers who were respecting the '841 patent, and Ranbaxy did not bring a declaratory judgment action against Eisai as to the DJ patents.

Teva's design is not to further the competing policy interests of the Hatch-Waxman Act or to achieve the goal of *Caraco*, namely, to "trigger [the first-filer's] 180-day 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). Ranbaxy (and twelve other generic companies) must wait until the '841 patent expires by virtue of its Paragraph III Certification with regard to that patent.

Rather than respect the patent as Ranbaxy and the others did by filing a Paragraph III Certification with regard to the '841 patent, Teva concocted an obviousness defense (which Teva changed completely and then withdrew as it became challenged in litigation) so that Teva could become a shared first-filer. That enabled Teva to obtain final FDA approval in April 2008, to threaten Eisai with the massive harm from a generic drug launch, and to force Eisai and the court into injunctive proceedings.

Teva admits that its generic product infringes the '841 patent, admits that the patent is valid, and knows that it will not persuade the district court that Eisai committed inequitable conduct (in light of the preliminary injunction from which Teva did not even appeal). Having been spurned rights to sell Aricept®, having had its meritless challenges to the '841 patent exposed, and having lost the leverage a threatened at-risk generic drug launch would cause Eisai, Teva developed another aggressive plan: it sought a declaratory judgment on the four DJ patents so that it could try to trigger Ranbaxy's exclusivity period (which arises only from its Paragraph IV Certifications as to the DJ patents) when Ranbaxy *cannot go to market*. But, a first-filer's exclusivity right is not an "injury" for Article III purposes that gives rise to "a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." *Janssen*, 540 F.3d at 1361. It certainly is not an injury caused by Eisai that amounts to an Article III controversy

between Teva and Eisai. The district court properly dismissed Teva's declaratory judgment complaint for lack of subject matter jurisdiction.

III. IN THE ALTERNATIVE, THE DISTRICT COURT PROPERLY EXERCISED DISCRETION TO DENY DECLARATORY RELIEF

"Since its inception, the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995); *MedImmune,* 549 U.S. at 136; 28 U.S.C. § 2201(a) (using the permissive phrase "may declare"). "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996).

The district court is vested with discretion to dismiss an action "because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp." *MedImmune,* 549 U.S. at 136 (citations omitted). For example, the court may exercise discretion to decline an action when it believes judicial resources would be better reserved for other actions closer to the central objectives of declaratory proceedings. *E.g., EMC*, 89 F.3d at 814.

Teva argues (Teva Br. at 42-43) that Congress eliminated equitable discretion, relying on the statutory provision that "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." 35 U.S.C. § 271(e)(5) (emphasis added). Teva affirmatively misreads this statute. The phrase "shall have subject matter jurisdiction" describes the *power* vested in the district court. It is silent about how district courts may *exercise* the granted power. A declaratory judgment is a remedy in equity, *Samuels v. Mackell*, 401 U.S. 66, 70 (1971), and a "major departure from the long tradition of equity practice should not be lightly implied," *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). The Hatch-Waxman Act does not purport to convert an equitable remedy into a mandatory one.

While Teva cites *Bennett v. Spear*, 520 U.S. 154 (1997), for the general proposition that Congress can modify or abrogate prudential jurisdictional requirements (Teva Br. at 43 n.16), Teva ignores the later holding of the Supreme Court that "prudential standing doctrine . . . ***applies unless*** it is ***expressly*** negated." 520 U.S. at 163 (emphasis added). The Hatch-Waxman Act does not expressly negate the traditional and long-standing equitable discretion of the district courts in considering requests for declaratory relief.

Indeed, the "shall have jurisdiction" formulation is ubiquitous in the United States Code. *See*, *e.g.*, 2 U.S.C. § 179r ("The several district courts of the United States *shall have jurisdiction*, for cause shown, to prevent and restrain violations of section 179q(a) of this title."); 7 U.S.C. § 87f(h) (District courts "shall have jurisdiction" in cases arising under the grain standards statutes); 7 U.S.C. § 1642(e) ("The district courts of the United States *shall have jurisdiction* of violations of this chapter or the rules and regulations thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty" pertaining to the international wheat trade); 7 U.S.C. § 6009(a) ("The district courts of the United States *shall have jurisdiction* specifically to enforce, and to prevent and restrain a person from violating, this chapter or any plan or regulation issued under this chapter" relating to pecan promotion).

Teva attempts to draw support from one Senator's comments during the floor debates on the bill that became section 271(e)(5). (*See* Teva Br. at 43.) But that Senator's views are unilluminating because he was not purporting to explicate the difference between the presence of jurisdiction and the exercise of that jurisdiction to award equitable relief. He expressed displeasure with the Supreme Court's holding in *Wilton* that federal courts have equitable discretion to declare the rights of parties, and conflated the equitable discretion not to declare the rights of parties (at issue in *EMC*) with an abdication of jurisdiction in violation of

Cohens v. Virginia, 19 U.S. 264 (1821). That is obviously not true; a district court's discretionary power to grant declaratory relief is different from its jurisdiction to issue that relief. *See Calderon v. Ashmus*, 523 U.S. 740, 745 (1998) ("the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory judgments *in appropriate cases*") (emphasis added).

The Hatch-Waxman Act is a detailed piece of compromise legislation. Teva cannot seek to supplant the language of the statute with arguments about the views of one member of Congress. *Garcia v. United States*, 469 U.S. 70, 76 n.3 (1984).[9] If Congress meant to negate the equitable discretion of district courts, Congress could have and would have enacted that into the statute expressly.

Thus, even if Teva could prove that the district court was vested with jurisdiction consistent with Article III (which it cannot), the district court was "entitled" to exercise its discretion in deciding whether to grant declaratory relief. (A24 (citing *MedImmune*, 549 U.S. at 136; *Wilton*, 515 U.S. at 286-87).) The district correctly found that "declining jurisdiction would be consistent with the purposes of the Declaratory Judgment Act and properly conserve judicial resources." *Id.* The court was well aware of the background facts and history of

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[9] The Senator also stated that a case or controversy might not exist where the "patent owner and brand drug company have given the generic applicant a covenant not to sue." 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003). Teva does not argue that *this* statement constitutes the law.

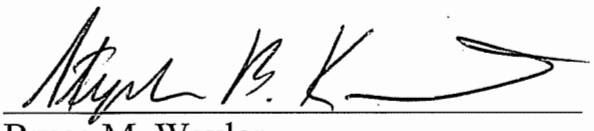
this action, and recognized the "multiple ANDAs and the relationship between Teva and Gate." (A24.) The equities favored declining jurisdiction rather than render essentially advisory opinions on whether Teva's second ANDA product infringed four patents (including two disclaimed patents), when the facts recounted above suggest that Teva would not be able to accelerate the first-filers (Ranbaxy and Teva) into the general market, and when Teva's desire was to deprive its competitor Ranbaxy of its statutory entitlement to a 180-day exclusivity period. (A24.) The district court did not abuse its discretion.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

For the reasons stated above, Eisai requests that this Court affirm the district court's September 9, 2009 order and judgment dismissing the action.

Dated: February 9, 2010

Respectfully submitted,



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CERTIFICATE OF SERVICE

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.
----------)

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by PAUL, HASTINGS, JANOFSKY & WALKER, Attorneys for Defendants-Appellees to print this document. I am an employee of Counsel Press.

On the **9th Day of February, 2010**, I served the within **Brief for Defendants-Appellees (confidential and non-confidential versions)** upon:

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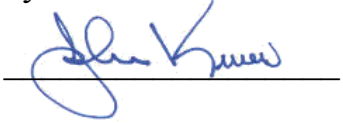
via Federal Express, overnight delivery, by causing 2 true copies of each to be deposited, enclosed in a properly addressed wrapper, in an official depository of the FedEx.

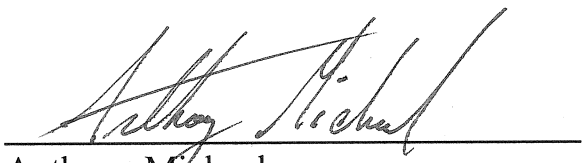
Unless otherwise noted, 12 copies of the confidential and 5 copies of the non-confidential brief will be filed with the Court via hand delivery as soon as possible after the court reopens following the snow emergency.

February 9, 2010



CERTIFICATE OF COMPLIANCE

I hereby certify pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and (C) that the foregoing BRIEF OF DEFENDANTS-APPELLEES contains 12,878 words, as measured by the word-processing system used in its preparation.



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Dated: February 9, 2010