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 PLAINTIFF-APPELLANT

Francis C. Lynch
Henry C. Dinger, P.C.
Laurie S. Gill
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

Counsel for Plaintiff-Appellant Teva Pharmaceuticals USA, Inc. through its GATE Pharmaceuticals division

NOVEMBER 30, 2009

COUNSEL PRESS, LLC (202) 783-7288 * (888) 277-3259 226656

CERTIFICATE OF INTEREST

Counsel for the appellant certifies the following:

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

   Teva Pharmaceuticals USA, Inc.

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

   Teva Pharmaceuticals USA, Inc.

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

Orvet UK Ltd.
Teva Pharmaceuticals Europe (Holland)
Teva Pharmaceutical Industries Ltd.
Teva Pharmaceutical Holdings Cooperatieve U.A.
Ivax LLC

4. All law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Francis C. Lynch
Henry C. Dinger, P.C.
Laurie S. Gill
John T. Bennett
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

Allyn Z. Lite
Michael E. Patunas
LITE DEPALMA GREENBERG & RIVAS, LLC
Two Gateway Center, 12th Floor
Newark, NJ 07102-5003
(972) 623-3000

TABLE OF CONTENTS

PAGE

Confidential Material Omitted

The confidential material omitted on pages 2, 5, 7 and 38 are subject to a protective order. The material relates to confidential business information.

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF RELATED CASES

No appeal in or from the case below was previously before this or any other appellate court. The following case pending in the United States District Court for the Middle District of North Carolina may be affected by this Court's decision in the pending case: *Apotex Inc. v. Eisai Inc. et al.*, 09-cv-00477 (M.D.N.C.) (declaratory judgment action brought by another generic company regarding the same four patents that are at issue in this case).

JURISDICTIONAL STATEMENT

The District Court had subject matter jurisdiction in this case under 28 U.S.C. §§1331 and 1338(a) because the case involves substantial claims arising under the United States Patent Act, 35 U.S.C. §1 *et seq.*, under 28 U.S.C. §§2201 and 2202 because the case presents an actual controversy concerning the validity and/or infringement of the patents-in-suit, and under 21 U.S.C. §355(j)(5)(C) as a civil action to obtain patent certainty brought in accordance with the terms of that statute.

Judgment in the District Court dismissing appellant's claims for lack of subject matter jurisdiction was entered on September 9, 2009. (A copy of the District Court's opinion is set forth in Addendum A.) Appellants filed a timely notice of appeal on September 28, 2009.

This Court has jurisdiction under 28 U.S.C. §1295(a)(1) because the appeal challenges a final decision of the United States District Court for the District of New Jersey in a case where the jurisdiction of that court was based, in whole or in part, upon 28 U.S.C. §1338 as a case relating to patents.

STATEMENT OF ISSUES

1. Whether the District Court erred in dismissing a civil action to obtain patent certainty under 21 U.S.C. §355(j)(5)(C) for lack of subject matter jurisdiction under Article III of the Constitution where the requisites of that statute were satisfied and where, unless appellant can obtain the declarations of patent non-infringement sought in this action, final FDA approval of the abbreviated new drug application **[confidential information deleted]** will be delayed by a third party's 180 days of generic exclusivity, perhaps indefinitely.

2. Whether a district court has the discretion to decline to hear a civil action to obtain patent certainty under 21 U.S.C. §355(j)(5)(C) where there is subject matter jurisdiction to hear that action under Article III of the Constitution.

3. If a district court has such discretion, whether the District Court in this case abused its discretion in declining to hear the claims in this case.

INTRODUCTION

The law of this Circuit governing subject matter jurisdiction over actions by generic drug companies seeking declaratory judgments of patent invalidity, unenforceability or non-infringement has undergone dramatic change in light of the Supreme Court's ruling in *MedImmune Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). In *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278 (Fed. Cir. 2008), this Court recognized that the Hatch-Waxman Act gave generic drug companies a legal interest in obtaining such judgments because, under the Act, such judgments directly affect the timing of FDA approval of generic drug applications. Accordingly, even if a patentee gives the generic drug company a covenant not to sue eliminating any possible liability for patent infringement, the generic drug company has standing to seek such a judgment to accelerate FDA approval of its application. The patentee's significant contrary interest in delaying that approval to forestall generic competition gives the dispute the definite and concrete adversity needed to satisfy the requirements of Article III of the Constitution.

This case does not require the Court to break any new ground. There is no principled distinction between this case and *Caraco*. In dismissing Teva's action seeking a declaration of non-infringement, the District Court

simply misread *Caraco*. The District Court erred as a matter of law in failing to follow *Caraco* and this Court should reverse.

STATEMENT OF FACTS AND OF THE CASE

1. *The Orange Book Patents.* Appellee Eisai is the holder of a New Drug Application ("NDA")[1] for two strengths of Aricept®, a prescription drug containing the active ingredient donepezil hydrochloride that is used in the treatment of senile dementia. (A102) Eisai listed five patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (a document generally referred to as the "Orange Book") with respect to Aricept®:

- U.S. Patent No. 4,895,841 (the "'841 patent") is directed to a class of compounds, including donepezil hydrochloride, and methods of treating senile dementia. This patent expires on Nov. 25, 2010.
- U.S. Patent No. 5,985,864 (the "'864 patent") is directed to certain polymorphic forms of donepezil hydrocholoride and processes for producing such polymorphs. This patent expires on Dec. 30, 2016.
- U.S. Patent No. 6,140,321 (the "'321 patent") is directed to certain additional polymorphic forms of donepezil hydrocholoride and processes for producing such polymorphs. This patent expires on Dec. 30, 2016.
- U.S. Patent No. 6,245,911 (the "'911 patent") is directed to certain polymorphic forms of donepezil and processes for producing such polymorphs. This patent expires on Dec. 1, 2018.

---

[1] The NDA is in the name of appellee Eisai Medical Research, Inc. which is the U.S. subsidiary of appellee Eisai Co., Ltd., a Japanese pharmaceutical company. For ease of reference, the appellees will be referred to collectively in this brief as "Eisai."

- U.S. Patent No. 6,372,760 (the "'760 patent") is directed to a formulation for an antidementia medication in which donepezil is the active ingredient, and methods for stabilizing such medications. This patent expires on March 31, 2019.

(A104) In this brief we will refer to the '864, '321, '911 and '760 patents as the "DJ Patents" or "later-expiring patents." Under the Hatch-Waxman Act, Eisai's listing of these patents constitutes a representation that a claim for infringing any of the listed patents "could reasonably be asserted" against any company that sells a generic donepezil product without a license from Eisai. 21 U.S.C. §355(b)(1).

Eisai disclaimed the '321 and '864 patents under 35 U.S.C. §253 in 2006 and 2007 respectively. (A390) Such disclaimers did not, however, remove either patent from the Orange Book and, as explained below, their continued presence in the Orange Book creates statutory obstacles to the approval of generic drugs, even after Eisai has disclaimed them.

2. *Teva's ANDA and Resulting Litigation.* In October 2004, appellant Teva[2] filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to sell a generic donepezil product. In its ANDA, Teva certified under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the four DJ Patents

---

[2] This action was brought in the name of Teva Pharmaceuticals USA, Inc. and its GATE Pharmaceuticals division. As explained below, Teva filed separate ANDAs **[confidential information deleted]** formulations of a donepezil product and FDA requested that Teva pursue the second ANDA in a different name for administrative convenience. (A378)

were invalid and/or would not be infringed by the generic product for which Teva sought FDA approval (the "Paragraph IV certification"). (A136) Teva also filed a certification under 21 U.S.C. §355(j)(2)(A)(vii)(III) that it did not seek FDA approval before the expiration of the '841 patent (the "Paragraph III certification"). The filing of the ANDA with the Paragraph IV certification constituted a statutory act of infringing the DJ Patents for purposes of establishing subject matter jurisdiction, entitling Eisai to bring suit. 35 U.S.C. §271(e)(2). Eisai did not sue Teva at this time.

In October 2005, Teva amended its ANDA, changing its Paragraph III certification as to the '841 patent to a Paragraph IV certification. (A191) Eisai brought an action against Teva under 35 U.S.C. §271(e)(2) for infringing the '841 patent in November 2005. That lawsuit triggered an automatic 30–month stay of FDA approval of Teva's ANDA. 21 U.S.C. 355(j)(5)(B)(iii). The FDA approved Teva's ANDA shortly after the 30-month stay expired in April 2008. (A280) However, in March 2008 Eisai sought and obtained a preliminary injunction against Teva's launching any generic donepezil hydrochloride product during the term of the '841 patent and Teva has not yet commenced commercial sale of any such product. *Eisai Co., Ltd v. Teva Pharmaceuticals USA, Inc.*, 2008 WL 1722098 (D. N.J. March 28, 2008).

3. *The GATE ANDA.* In November 2005, Teva filed a second ANDA for a generic donepezil product different

[confidential information deleted]. For administrative purposes, the FDA requested that Teva pursue the second ANDA in a different name and Teva re-filed the second ANDA in the name of its GATE Pharmaceuticals division. (A378) The second ANDA will be referred to as the "GATE ANDA" in this brief.

The GATE ANDA initially made Paragraph III certifications as to all five patents listed in the Orange Book for Aricept®. These certifications were later changed to Paragraph IV certifications for all five patents. (A20) In November 2007, Eisai sued GATE but only for the infringement of the '841 patent. This action was consolidated with Eisai's infringement action against Teva in early 2008 on the '841 patent and the preliminary injunction obtained against Teva's launching the product described in its ANDA applies as well to the product described in the GATE ANDA. (A243)

4. *Ranbaxy's ANDA and Shared Exclusivity.* Teva was not the first generic drug company to file an ANDA with a paragraph IV certification for a donepezil product. In 2003, the Indian pharmaceutical company Ranbaxy Laboratories Ltd. ("Ranbaxy") filed an ANDA that contained a Paragraph III certification as to the '841 patent and a Paragraph IV certification as to the DJ Patents. Eisai did not sue Ranbaxy for infringing the DJ Patents. (A6-7)

By virtue of being the first company to file a generic drug application containing a Paragraph IV certification as to the DJ Patents, Ranbaxy became entitled to a 180–day period of generic "exclusivity" with respect to the DJ patents. 21 U.S.C. §355(j)(5)(B)(iv) (old).[3] When Teva amended its ANDA to contain a Paragraph IV certification as to the '841 patent, it became the "first filer" as to that patent and, under FDA precedent, thereby

---

[3] Congress amended the exclusivity provisions of the Hatch-Waxman Act in the Medicare Modernization Act of 2003 ("MMA"). However, the MMA provided that the earlier provisions would continue to apply to ANDAs filed with Paragraph IV certifications before December 8, 2003, as well as to ANDAs filed after that date if another generic drug company had filed an ANDA with a Paragraph IV certification for the same listed drug before that date. *Caraco*, 527 F.3d at 1283 n.2. Ranbaxy's ANDA was filed in August 2003, and so questions of exclusivity pertaining to that ANDA and all later ANDAs filed with respect to Aricept®, are governed by pre-MMA law.

Appellants have included as Addendum B to this brief a copy of the pre-MMA version of the pertinent provision of the Hatch-Waxman Act, 21 U.S.C. §355. Citations to the pre-MMA version of the statute in this brief will be in the form "21 U.S.C. §___ (old)."

also became entitled to this statutory "exclusivity" benefit. *See Dr. Reddy's Laboratories, Inc. v. Thompson*, 302 F. Supp. 2d 340, 359 (D. N.J. 2003). By virtue of this "shared exclusivity," the FDA was in a position to give final approval to either Teva's or Ranbaxy's ANDA without regard to the other's exclusivity, but approval of any third ANDA for donepezil — including the GATE ANDA — would be subject to both Teva's and Ranbaxy's exclusivity period.

Under the applicable law, these exclusivity periods can be triggered in one of two ways: either the first filer's commencement of commercial sale of its generic product or a final, unappealable judgment obtained by any filer that all of the patents on which the first filer's exclusivity is based are invalid, unenforceable or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv) (old); *see* Public Law No. 108-173 §§ 1102(b)(1), (b)(3), 21 U.S.C.A § 355 note (Effective and Applicability Provisions). Because Ranbaxy filed a Paragraph III certification as to the '841 patent, it cannot receive FDA approval to sell its generic donepezil product before the '841 patent expires in November 2010.

Recent published reports raise questions whether Ranbaxy will obtain FDA approval even then. On February 25, 2009, the FDA issued a press release announcing that Ranbaxy had submitted falsified data and test results

in approved and pending drug applications filed with the FDA.[4] The press release also announced that an Import Alert barring entry of all finished drug products from a Ranbaxy tablet-making facility in India remains in effect. The *Wall Street Journal* reported on November 10, 2009 that Ranbaxy's Chief Executive stated that Ranbaxy was still in discussions with the FDA and that it would take "a long time" to resolve the FDA issues.[5] These FDA problems may well prevent Ranbaxy from launching its donepezil tablet product when the '841 patent expires in late 2010.[6]

5. *Teva's and GATE's Civil Action to Obtain Patent Certainty.* Although the Paragraph IV certifications in both the Teva and GATE ANDAs as to the four DJ Patents constituted statutory acts of infringing those patents for jurisdictional purposes, 35 U.S.C. §271(e)(2), Eisai did not bring an action for patent infringement of those patents within 45 days of its receipt of the Paragraph IV certifications. Accordingly, 21 U.S.C.

---

4 U.S. Food and Drug Administration, Feb. 25, 2009 News Release, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149532.htm.

5 Nikhil Gulati, *Ranbaxy: FDA Issues Will Take Time to Resolve*, Wall St. J. Nov. 10, 2009, *available at* http://online.wsj.com/article/SB10001424052748704402404574524983332509354.html

6 http://www.ranbaxy.com/manufacturing/dosage.aspx

§355(j)(5)(C) specifically authorized the commencement of a civil action against Eisai "for a declaratory judgment that the patent[s] ... will not be infringed by the drug for which the [ANDA] applicant seeks approval." Teva brought such an action against Eisai in May 2008, and sought a declaration that the product described in the GATE ANDA infringed none of the four DJ Patents and that the product described in the Teva ANDA did not infringe the two DJ Patents that Eisai had not disclaimed. (A33-41)

The difference in claims reflected the different effects that Ranbaxy's exclusivity has on the Teva and GATE ANDAs respectively. Because Teva had final approval on the earlier ANDA and shared exclusivity with Ranbaxy as to that ANDA, the only obstacles to Teva's launching the generic product described in that ANDA were Eisai's two non-disclaimed DJ Patents and the pending preliminary injunction in Eisai's suit against Teva and GATE on the '841 patent. Since Teva's ability to launch would not be affected by a judgment as to the disclaimed patents, Teva had no legally cognizable interest in establishing that the product covered in the earlier ANDA would not infringe the two disclaimed patents. As a result, it sought no declaratory judgment as to them.

However, Teva did have a cognizable legal interest in establishing that the product in the GATE ANDA did not infringe the disclaimed patents. In addition to the obstacles faced by Teva as to its earlier ANDA (the non-disclaimed patents and the preliminary injunction), the product in the GATE ANDA is subject to Ranbaxy's 180-day exclusivity period. Under the pre-MMA provisions that govern this case, *see* n. 3 *supra*, the commencement of Ranbaxy's exclusivity period is triggered by the earlier of (i) Ranbaxy's "first commercial marketing" of the product described in its ANDA, and (ii) a final, unappealable court decision holding the four DJ Patents (including the two disclaimed patents) invalid, unenforceable or not infringed. 21 U.S.C. §355(j)(5)(B)(iv) (old); *see* Public Law No. 108-173 §§ 1102(b)(1), (b)(3), 21 U.S.C.A § 355 note (Effective and Applicability Provisions). Since Ranbaxy is unable to launch before the November 25, 2010 expiration of the '841 patent — and seems unlikely to be able to launch immediately after that expiration — the only way to trigger Ranbaxy's exclusivity before that date would be to obtain a judgment that the four DJ patents (including the two disclaimed patents) are invalid, unenforceable or not infringed. Accordingly, Teva sought a declaration that the product described in the GATE ANDA would not infringe any of the four DJ Patents.

After the initial complaint was filed, the parties negotiated an agreement under which Eisai gave Teva a covenant not to sue on the non-disclaimed DJ Patents with respect to both ANDAs. (A385-388) As a result of that covenant, Teva and GATE filed an Amended Complaint in which all claims made with respect to the Teva ANDA were removed. (A81-87) Because Ranbaxy's exclusivity did not stand in the way of FDA final approval of the Teva ANDA, and because of the disclaimers and the covenant not to sue, the four DJ Patents no longer presented any obstacle to the launch of the product in the Teva ANDA. (Teva continues to litigate over the '841 patent in collateral litigation with respect to both the Teva ANDA and the GATE ANDA.)

But Ranbaxy's exclusivity continued to present an obstacle to the launch of the product described in the GATE ANDA. Accordingly, the Amended Complaint sought a declaration that the product in the GATE ANDA did not infringe any of the DJ Patents. (A86)

Eisai moved to dismiss the Amended Complaint for lack of subject matter jurisdiction. (A29) On September 9, 2009, the District Court granted Eisai's motion to dismiss. (A1) A timely notice of appeal from the dismissal was filed on September 28, 2009. (A32)

SUMMARY OF ARGUMENT

This Court's decision in *Caraco* requires the reversal of the dismissal of Teva's claim for a declaration that the product referenced in the GATE ANDA does not infringe any of the DJ Patents. There is no principled distinction between this case and *Caraco*. *Caraco* recognized that even where the patentee has given a covenant not to sue for infringement of a particular patent, a generic company has standing to seek a judgment of non-infringement as to that patent because the Hatch-Waxman Act makes the timing of FDA approval of the generic company's ANDA turn on such a judgment, and not merely on non-liability. That is the precise situation in this case.

The District Court's efforts to distinguish *Caraco* are entirely unpersuasive. The District Court first erred by concluding that the pendency of a preliminary injunction against Teva makes this case closer to *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), than to *Caraco* by creating an immediate obstacle to FDA approval in addition to the first filer's exclusivity. However, Caraco faced a similar immediate obstacle in the form of the statutory 30–month stay of FDA approval that arose when the patentee sued Caraco on its earliest expiring Orange Book patent. That stay had many months to run when the patentee in *Caraco*

moved to dismiss. Like the preliminary injunction in this case, the 30–month stay in *Caraco* would dissolve upon Caraco's prevailing in the patentee's suit on the earliest expiring patent. This possibility of eliminating the temporary obstacle to FDA approval by successful litigation on the earliest-to-expire patent distinguishes both this case and *Caraco* from *Janssen*, where the generic company had *stipulated* that the product in its ANDA infringed a valid and enforceable patent. The stipulation in *Janssen* was final. Neither the preliminary injunction in this case nor the 30–month stay in *Caraco* are final. Absent such a *final* obstacle to FDA approval, the *Janssen* Court acknowledged that *Caraco* was controlling.

The District Court further erred in viewing the uncertainty whether the preliminary injunction would be lifted before the expiration of the '841 patent as undermining the ripeness of the claim. But it was equally uncertain whether Caraco would succeed in obtaining a judgment sufficient to lift the 30–month stay. This Court in *Caraco* recognized that such uncertainties did not prevent a claim for declaratory relief from being ripe. Where the issues are suitable for judicial resolution and where delay would visit harm on the party seeking such relief — both circumstances are present here as in *Caraco* — the claim is ripe.

The District Court mistakenly viewed Teva's shared exclusivity with Ranbaxy as weighing against jurisdiction in this case. Teva is actively litigating the merits of its challenge to the '841 patent in a consolidated proceeding with respect to both the Teva ANDA and the GATE ANDA. Success in that case could trigger Teva's exclusivity before the expiration of the '841 patent. But, whether or not Teva succeeds in obtaining a favorable judgment before the expiration of the '841 patent, Teva must also obtain a judgment with respect to the DJ patents in order to trigger Ranbaxy's exclusivity with respect to the GATE ANDA.

If this Court finds, as it should, that there was jurisdiction under Article III to resolve Teva's civil action to obtain patent certainty, then the case must be reversed. Although the District Court purported to decline jurisdiction on discretionary as well as constitutional grounds, Congress has withdrawn from district courts any discretion to decline jurisdiction where there is a dispute justiciable under Article III. In 35 U.S.C. §271(e)(5), Congress directed that district courts "shall" have jurisdiction over such cases. The legislative history of this statute makes it quite clear that Congress intended that generic companies have the same *right* to obtain prompt judicial resolution of patent disputes that brand companies enjoy.

Even if there were discretion, this Court has stressed the importance of declaratory judgment actions in resolving patent disputes and has reversed discretionary dismissals of such actions where the exercise of jurisdiction would advance important statutory goals. Because the exercise of jurisdiction here would advance the statutory goal of accelerating the introduction of generic drugs consistent with the rights of patent owners and because the District Court failed to articulate a legitimate rationale for not hearing Teva's claim, the District Court abused its discretion.

ARGUMENT

I. STANDARD OF REVIEW

The existence of an "actual controversy" sufficient to sustain federal subject matter jurisdiction in a declaratory judgment action is a question of law, reviewed by this Court *de novo*. *Caraco*, 527 F.3d at 1290; *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1336 (Fed. Cir. 2007). Whether the civil action to obtain patent certainty under the MMA give district courts any discretion to refrain from asserting jurisdiction over such an action is also a question of law reviewed *de novo*. The question whether a district court properly declined to hear a claim for declaratory relief, notwithstanding the existence of subject matter jurisdiction under Article III is reviewed under a constrained abuse of

discretion standard. "[T]he exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007).

II. THERE IS NO PRINCIPLED BASIS FOR DISTINGUISHING THIS CASE FROM *CARACO*, AND THEREFORE THE DISMISSAL OF APPELLANTS' CIVIL ACTION TO OBTAIN PATENT CERTAINTY MUST BE REVERSED.

A. THE STATUTORY FRAMEWORK CREATED BY THE HATCH-WAXMAN ACT.

Congress enacted the Hatch-Waxman Act in 1984 with the goal of accelerating the introduction of less costly generic drugs. In enacting the Act, "Congress sought to get generic drugs into the hands of patients at reasonable prices — fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

The Hatch-Waxman Act seeks to achieve this goal by permitting generic drug companies to file ANDAs with respect to generic drug formulations that are shown to be "bioequivalent" to previously approved reference drugs. Proof of bioequivalence allows the FDA to apply to the generic drug its earlier conclusion that the reference drug is safe and effective without requiring the submission of new clinical tests involving the generic drug. *Id.* at 73.

Since many reference drugs are protected by one or more patents, Congress recognized that uncertainty regarding the application of these patents would delay the introduction of generic drugs. Accordingly, Congress sought to promote the quick resolution of patent disputes by (i) making the submission of an ANDA with a Paragraph IV certification an act of patent infringement sufficient to establish jurisdiction over a patent infringement action, and (ii) encouraging patentees to initiate such infringement actions promptly by giving an automatic 30–month stay of FDA approval of the ANDA if the patentee brings suit within 45 days of receiving notice of the ANDA. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1339 (Fed. Cir. 2003). As this Court noted, the Act "provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve *any* dispute concerning infringement and validity." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added). Congress' expectation was that the resolution of patent disputes would occur while the FDA reviewed the ANDA, and, if the ANDA applicant prevailed in the patent litigation, it could launch immediately.

Experience under the Hatch-Waxman Act demonstrated, however, that in many situations it served the economic interest of patentees to refrain from bringing infringement actions on Orange Book patents notwithstanding the incentive of the 30–month stay. For example, a patentee would sue on some Orange Book patents shortly after the submission of an ANDA with a Paragraph IV certification, while holding the other patents in reserve to assert against a generic company when it later attempted to launch a competing generic product. Because the patentee obtained the benefit of the 30–month stay by suing on only one patent, the patentee's interests in delaying generic competition as long as possible were served by this strategy.[7]

Another situation in which refraining from suit would serve the patentee's interest in delaying generic competition involves multiple ANDA filers with respect to the reference drug. If the first ANDA filer makes a Paragraph IV certification to more than one patent and loses the resulting litigation with respect to the earlier expiring patent under 35 U.S.C. §271(e), then the first filer will not receive FDA approval to launch until that patent

---

[7] This precise situation was presented in *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.* ("*Teva v. Novartis*"), 482 F.3d 1330 (Fed. Cir. 2007).

expires. By virtue of being the first ANDA filer to make a Paragraph IV certification to the later-expiring patent, the first filer will nonetheless be entitled to a 180-day period of exclusivity. As a result, subsequent ANDA filers making Paragraph IV certifications will be unable to obtain FDA approval until at least 180 days after the earlier-expiring patent expires, unless they can trigger the earlier commencement of the first filer's exclusivity by securing a final judgment of invalidity, unenforceability or non-infringement of the later-expiring patents before the expiration of the earlier-expiring patent.

Under such circumstances, there is no advantage to the patentee from suing the subsequent filer immediately. The patentee's success in the litigation would still leave the subsequent filer unable to launch until 180 days after the first filer's launch, exactly the same result as if the patentee had brought no suit at all. But if the subsequent filer prevailed in the litigation, then the first filer's exclusivity would be triggered before the first filer could launch and the patentee might face competition from the subsequent filer before the expiration of the earliest-expiring patent. For the patentee, litigation against the subsequent filer in this situation offers no upside and a considerable downside.

These two situations illustrate how the Congressional goal of hastening the introduction of generic drugs by encouraging the prompt resolution of patent disputes could be undermined by patentees. The obvious solution was to permit generic companies to initiate the resolution of these patent disputes themselves by bringing declaratory judgment actions against the brand company patentees. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1072-73 (D.C. Cir. 1998). Congress gave such permission in the MMA by providing that generic companies as well as patentees could bring a "civil action to obtain patent certainty," 21 U.S.C. §355(j)(5)(C). *See Teva v. Novartis*, 482 F.3d at 1342-44 (discussing legislative history). The instant appeal seeks review of the District Court's dismissal of such an action.

B. SUBJECT MATTER JURISDICTION OVER DECLARATORY JUDGMENT ACTIONS IN THE FEDERAL CIRCUIT.

When Congress created the "civil action to obtain patent certainty," it was unclear whether this Court would find that the exercise of subject matter jurisdiction over such claims conformed to the justiciability requirements of Article III. *See Mova*, 140 F.3d at 1073. The long-standing principle applied by this Court was that there was no subject matter jurisdiction over a suit seeking a declaration of invalidity, unenforceability or non-infringement unless:

> First, the defendant's conduct must have created on the part of plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the device or have prepared to produce that device.

Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 955 (Fed.Cir.1987).

In this Court's first case considering subject matter jurisdiction over a "civil action to obtain patent certainty," this Court ruled that Article III required proof of a "reasonable apprehension of imminent suit," and that, in the absence of an express threat of litigation or some other affirmative step by the patentee sufficient to give rise to an objectively reasonable fear of imminent patent litigation, the test could not be satisfied. *Teva Pharms. USA, Inc. v. Pfizer*, 395 F.3d 1324, 1332 (Fed Cir. 2005). Since it was easy for patentees seeking to delay patent certainty to refrain from making the kind of threat required by this Court's decisions, there were few if any circumstances in which a civil action to obtain patent certainty under 21 U.S.C. §355(j)(5)(C) could be brought. Declaratory relief was effectively made unavailable in precisely those circumstances in which Congress considered it most needed.

In *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 n.11 (2007), the Supreme Court ruled that this Court's "reasonable apprehension of suit" requirement was inconsistent with Article III principles and stressed that the proper test for the justiciability of declaratory judgment actions was the "definite and concrete controversy" test set forth in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). This Court conformed its jurisdictional law in ANDA cases to the *Aetna/MedImmune* standard in *Teva v. Novartis*, ruling that proof of a reasonable apprehension of suit, imminent or otherwise, was no longer required.[8] 482 F.3d at 1346-47.

In *Teva v. Novartis*, as in this case, the patentee brought an infringement suit under 35 U.S.C. §271(e) on a first-to-expire compound patent but did not bring suit on four later expiring patents. For purposes of creating that 30-month stay, it made no difference whether the patentee sued on one patent or all five. By suing on only one patent, the patentee was able to hold the other four patents in reserve to assert when the 30-month stay was about to expire and thus preserve the chance to prevent generic

---

[8] The Court did not address the second component of the traditional test, i.e. whether the declaratory judgment plaintiff had taken concrete steps toward carrying out arguably infringing activities. However, in ANDA cases such as this one that test is satisfied because by filing an ANDA with a Paragraph IV certification, the generic company commits a statutory act of infringement. *Teva v. Pfizer*, 395 F.3d at 1332.

competition even beyond the dissolution of the 30-month stay. On the other hand, suing on all five patents would create an opportunity for the generic company to obtain a judgment of invalidity or non-infringement as to all five, a judgment that would trigger FDA approval and expose the patentee to immediate generic competition. As this Court noted, Congress created the "civil action to obtain patent certainty" in the 2003 MMA to prevent patentees from "gaming" the Hatch-Waxman Act in this fashion. 482 F.3d at 1342. The Court found subject matter jurisdiction under Article III over the generic company's claim for declaratory relief and reversed the dismissal.

The ability of generic drug companies to seek declaratory judgments under 21 U.S.C. §355(j)(5)(C) put an end to the strategy of delaying generic entry by simply declining to bring suit under 35 U.S.C. §271(e). So brand drug companies adopted a new strategy, illustrated by the facts presented in *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). The patentee, Forest, sold a successful antidepressant with escitalopram as its active ingredient. Forest listed two patents in the Orange Book for its product, a compound patent covering escitalopram itself that expired in 2012, and a patent covering crystalline particles of escitalopram of particular sizes that expired in 2023. *Id.* at 1286. The first ANDA filer,

Ivax, filed a Paragraph IV certification as to both patents. Forest sued Ivax for infringing the compound patent but not the particle patent. Forest prevailed in the litigation, so Ivax was precluded from launching until the compound patent expired in 2012.

A subsequent ANDA filer, Caraco, also submitted Paragraph IV certifications as to both patents. In mid-2006, Forest sued Caraco for infringing the compound patent, but not the particle patent. Because Ivax was the first ANDA filer to submit a Paragraph IV certification as to the particle patent, Caraco's ability to launch its generic escitalopram product was blocked by Ivax's 180–day exclusivity period. Since Ivax had lost its case on the compound patent, Ivax could not launch its product before 2012. Thus, *even if Caraco succeeded in its challenge to the first-to-expire compound patent*, Caraco could not obtain FDA final approval to launch until at least six months after the expiration of that patent, unless it could trigger the earlier commencement of Ivax's exclusivity period. The only way for Caraco to trigger Ivax's exclusivity before the expiration of the compound patent — a path that would expose Forest to competition from multiple generic companies — was to obtain a judgment of invalidity, unenforceability or non-infringement with respect to the particle patent.

Under this Court's pre-*MedImmune* jurisprudence, Forest could prevent Caraco from obtaining such a judgment simply by refraining from suit.

When Forest did not sue on the particle patent within 45 days, Caraco filed an action seeking a declaration that its product did not infringe the particle patent. Forest moved to dismiss on the authority of *Teva v. Pfizer*. But while its motion was pending, this Court decided *Teva v. Novartis*, and thereby undercut the basis for Forest's motion.

Determined to prevent Caraco from triggering Ivax's exclusivity, Forest gave Caraco a covenant not to sue for infringement of the particle patent. Relying on this Court's decision in *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed. Cir. 1995), Forest argued that such a covenant eliminated any Article III case or controversy between Forest and Caraco over the particle patent.

The district court in that case dismissed Caraco's declaratory judgment action, but this Court reversed. The Court recognized that in most situations, the sole legal interest of an accused infringer in establishing invalidity or non-infringement is the avoidance of liability for patent infringement. As the Court ruled in *Super Sack*, an unconditional covenant not to sue for infringing the patent eliminates that legal interest, and with it the standing of the accused infringer to seek a ruling that it is not liable for

patent infringement. Upon receiving such a covenant not to sue, a party is ordinarily free to sell its arguably infringing product immediately.

However, the situation is quite different in cases governed by the Hatch-Waxman Act. Independent of the interest in avoiding liability, an ANDA applicant has a legal interest in obtaining a *judgment* establishing invalidity or non-infringement because such a *judgment* affects the timing of FDA approval. Under the Hatch-Waxman Act, (i) a district court *judgment* of invalidity or non-infringement causes the automatic 30–month stay of FDA final approval to dissolve, 21 U.S.C. §355(j)(5)(B)(iii)(I)[9], and (ii) an unappealed district court judgment or final court of appeals decision of invalidity, unenforceability or non-infringement triggers the 180–day exclusivity period of the first ANDA filer to include a Paragraph IV certification, 21 U.S.C. §355(j)(5)(B)(iv) (old)[10]; *see* Public Law No. 108-173 §§ 1102(b)(1), (b)(3), 21 U.S.C.A § 355 note (Effective and Applicability Provisions). In the Hatch-Waxman Act context, a covenant

---

[9] This is true under both the pre-MMA and post-MMA verions of the Act.

[10] The MMA eliminated the litigation trigger on the first filer's 180–day exclusivity period, but provides that that exclusivity is forfeited if the first filer does not commence marketing of the generic drug within a specified period following a final court decision of invalidity, unenforceability or non-infringement. 21 U.S.C. §§355(j)(5)(D)(i)(I)(bb), 355(j)(5)(D)(ii).

not to sue does not have the same effect as a favorable judgment because only a *judgment* affects the timing of FDA approval.

In *Caraco,* this Court ruled that because (i) the FDA approval required for commercial sale turns on *judgments* and not merely on *non-liability*, and (ii) the patentee's conduct (in listing the patents in the Orange Book, refraining from suit and covenanting not to sue) interfered with the ability of an ANDA applicant to obtain such judgments, an ANDA applicant has standing under Article III to seek such a judgment even if the patentee's covenant not to sue eliminated any exposure to liability for patent infringement. 527 F.3d at 1296-97. Moreover, such a claim was ripe and the covenant not to sue did not render it moot. *Id.* This Court reversed the dismissal for want of subject matter jurisdiction and remanded for resolution of Caraco's claim for declaratory relief on the merits.

C. THE CLAIM FOR DECLARATORY RELIEF IN SUPPORT OF THE GATE ANDA IS INDISTINGUISHABLE FROM THE CLAIM IN *CARACO.*

The District Court's dismissal of the claim for declaratory relief in this case cannot stand because it is squarely inconsistent with *Caraco.* The circumstances here are indistinguishable from those in *Caraco.* With respect to the GATE ANDA, Teva, like Caraco, is a subsequent filer that has filed a Paragraph IV certification as to all Orange Book patents that pertain to the

reference drug. As in *Caraco*, the GATE ANDA is subject to the 180–day exclusivity period of a first filer (here Ranbaxy). And, as in *Caraco*, in the absence of a judgment adverse to the patentee, the first filer's exclusivity cannot commence before the expiration of the earliest-to-expire compound patent.[11]

As in *Caraco*, the triggering of the first filer's exclusivity before the expiration of the earliest-to-expire patent would present the patentee (here Eisai) with the risk of earlier competition from more than one generic product. As in *Caraco*, Eisai sought to forestall this risk by bringing suit only on the earliest-to-expire patent (the '841 patent) and relinquishing any possibility of liability on the later-expiring DJ Patents.[12] Teva's interest with respect to the GATE ANDA is exactly the same as Caraco's. The Article III analysis applied by this Court in *Caraco* requires the identical result here.

---

[11] It does not matter that the inability of the first filer to launch before the expiration of the earliest expiring patent results from the first filer's Paragraph III certification (as here) or from the patentee's obtaining final determinations of validity and infringement (as in *Caraco*). What is critical is that without obtaining a judgment, the subsequent filer cannot trigger the first filer's exclusivity period before the expiration of the first expiring patent (or even after that expiration if, for whatever reason, the first filer does not immediately launch upon expiration).

[12] That Eisai's response involved a combination of covenants not to sue and disclaimers while there was only a covenant not to sue in *Caraco* makes no difference. The result is the same, i.e. the elimination of any possibility of infringement liability without an adverse judgment.

D. THIS COURT'S *JANSSEN* DECISION DOES NOT REQUIRE DISMISSAL OF THE CLAIM FOR DECLARATORY RELIEF.

The District Court refused to follow *Caraco* for reasons that cannot withstand scrutiny. The principal reason given by the District Court for refusing to follow *Caraco* was that this case is closer to *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), than to *Caraco*. (A22) This conclusion turns on a failure to appreciate the circumstances present in *Caraco* (and in this case) and how they differ from those in *Janssen*.

In *Janssen*, the patentee (Janssen) listed three Orange Book patents with respect to the anti-psychotic compound risperidone. The first-to-expire patent was a compound patent covering risperidone, while the two later expiring patents covered specific formulations of risperidone and methods of preparing those formulations. The first ANDA filer (Teva) filed a Paragraph III certification as to the compound patent and a Paragraph IV certification as to the other two patents. Thus, the first filer could not obtain FDA approval to launch until after the expiration of the compound patent.

In this regard, the first filer in *Janssen* was in the same position as the first filer in *Caraco*.[13]

The subsequent ANDA filer, Apotex, filed a Paragraph IV certification as to all three Orange Book patents. As in both *Caraco* and this case, the patentee sued Apotex on the compound patent but not the two later expiring patents. Apotex responded, as did Caraco and Teva here, by seeking a declaratory judgment of non-infringement as to the later-expiring patents. As in *Caraco* and in this case, the patentee gave Apotex a covenant not to sue on those patents and successfully moved to dismiss.

The *Janssen* Court affirmed the dismissal, distinguishing *Caraco* because Apotex, unlike Caraco and Teva, had *agreed* to be bound in its litigation with Janssen over the compound patent by the result of an infringement suit that Janssen had brought against a third generic drug company on the compound. When Janssen prevailed in that third party litigation, Apotex's agreement to be bound by that case resulted in a binding

---

[13] That the inability of the first filer in *Caraco* to obtain final approval resulted from an unsuccessful challenge to the compound patent rather than a Paragraph III certification, as in *Janssen*, does not change the fact that the first filer in both cases could not obtain final FDA approval until the expiration of the compound patent.

stipulation that the compound patent was valid and infringed by Apotex's product.

The stipulation was critical to this Court's determination that *Caraco* was not controlling and that the dismissal in *Janssen* should be affirmed. The Court was unmistakably clear on this point: "if Apotex had not stipulated to validity of the [compound] patent, then *Caraco* would have been controlling." *Janssen*, 540 F.3d at 1360. *Accord, Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 360-62 (D. Del. 2009).

Of course, Teva, like Caraco and unlike Apotex in *Janssen*, has not stipulated that it cannot prevail in the litigation over the compound patent in this case. Teva, like Caraco, is engaged in ongoing litigation challenging the enforceability of the '841 patent. Accordingly, *Caraco*, not *Janssen*, is controlling, as this Court in *Janssen* acknowledged.

The District Court recognized that Teva made no stipulation comparable to Apotex's stipulation in *Janssen*, but pointed to the preliminary injunction that *currently* prevents Teva from launching any generic donepezil product. The District Court deemed that obstacle to be comparable to the stipulation in *Janssen*. (A22)

However, the obstacle to *immediate* FDA approval presented by the preliminary injunction does not distinguish this case from *Caraco* at all. As

this Court noted in *Caraco*, the patentee's commencement of litigation on the compound patent within 45 days of Caraco's ANDA created an automatic 30–month stay of FDA approval. That stay remained in effect when Forest moved to dismiss Caraco's claim for declaratory relief on the later-expiring patents.[14]

There is no principled distinction between the obstacle created by the 30–month stay in *Caraco*, and the obstacle created by the preliminary injunction in this case. In both cases, the generic drug company seeking declaratory relief actively continued to litigate with respect to the compound patent, and the patentee's claim in neither case had been finally resolved. In both cases, the success of the generic company on the merits of the suit with respect to the compound patent would have eliminated the obstacles to FDA approval created by the stay and the preliminary injunction respectively.[15] Both this case and *Caraco* are thus distinguishable from *Janssen*, where the

---

[14] Caraco filed its ANDA in May 2006. *Caraco*, 527 F.3d at 1288. Forest promptly sued on the compound patent and triggered the 30–month stay. *Id.* at 1288 & n.7. That stay did not expire until late 2008, long after the District Court granted the motion to dismiss.

[15] Obviously, the generic company's success on the merits would result in the vacation of a preliminary injunction. A final judgment on the merits in favor of the generic company also results in the dissolution of the 30–month stay and the authorization of immediate FDA final approval, subject to any applicable exclusivities. 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa).

generic company, *by virtue of its stipulation*, could no longer defend against the infringement claim brought on the compound patent and was *finally* precluded from launching before the expiration of that patent. As this Court recognized in *Janssen*, absent such a stipulation, the reasoning of *Caraco* compels a finding of subject matter jurisdiction.

E. TEVA'S CIVIL ACTION FOR PATENT CERTAINTY IS BOTH RIPE AND NOT MOOT.

The District Court failure to recognize the effect of the 30–month stay in *Caraco* also led that court to mistakenly view Teva's claim with respect to the DJ Patents as unripe. The court observed: "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 [compound] patent, the potential injury alleged by Teva here lacks the sufficient immediacy and reality required to establish declaratory judgment jurisdiction." (A23)

However, Caraco was in the same position as Teva. It was also entirely "speculative" whether Caraco would prevail in its litigation with Forest on the compound patent. After all, unlike the situation here, the compound patent in *Caraco* had been found valid and enforceable after a five-day trial involving another ANDA applicant, a determination later affirmed by this Court. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d

1263 (Fed. Cir. 2007). While Caraco was not formally bound by this decision, certainly it faced an uphill battle. In the meantime, of course, Caraco was precluded from launching because of the 30–month stay. Because this Court found that Caraco's claim was ripe, Teva's claim is ripe as well.

The ripeness of Teva's claim for declaratory relief follows as well from the ripeness principles followed by this Court in *Caraco*. As this Court noted, the ripeness inquiry "requires an evaluation of 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration'." *Caraco*, 527 F.3d at 1294-95 (quoting *Abbott Las. v. Gardner*, 387 U.S. 136, 149 (1967)). Both factors support a finding a ripeness here, as they did in *Caraco*.

Certainly, the underlying patent issues are justiciable. Courts routinely assess the validity and enforceability of Orange Book patents and whether products described in ANDAs infringe such patents.

Likewise, Teva faces hardship if it is unable to obtain a judgment on the DJ Patents. If, as Teva contends, it does not infringe the DJ patents, then "delaying court consideration of [Teva's] declaratory judgment action [as to those patents] delays the date on which the FDA is authorized to approve [the GATE] ANDA," "until at least 181 days after the [compound] patent

expires." *Caraco*, 527 F.3d at 1295-96. Teva's claim is ripe for the same reasons that Caraco's claim was ripe.

In addition, Teva's claim with respect to the GATE ANDA is not moot for the same reasons that Caraco's claim was not moot. Unlike the typical situation in which a covenant not to sue moots a controversy over infringement by permitting the accused infringer to launch immediately with no exposure for patent infringement liability, in the Hatch-Waxman context, the absence of a *judgment* has adverse legal consequences apart from any exposure to liability. *Caraco*, 527 F.3d at 1296-97. Teva's legal interest in avoiding those consequences prevents the claim as to the DJ Patents from being moot.

F. THAT RANBAXY'S EXCLUSIVITY RIGHTS DO NOT PRECLUDE TEVA FROM LAUNCHING THE DONEPEZIL PRODUCT DESCRIBED IN THE TEVA ANDA HAS NO BEARING ON TEVA'S STANDING TO SEEK ACCELERATION OF FDA APPROVAL OF THE GATE ANDA.

A third reason given by the District Court for its finding of no jurisdiction is that Teva is not precluded from launching the product described in its first ANDA, even if the product in the GATE ANDA cannot be approved until Ranbaxy's exclusivity period has run. The District Court noted that "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'." (A21 *quoting Caraco*, 527 F.3d at 1296).

However, nothing in the Hatch-Waxman Act precludes generic companies from pursuing more than one ANDA to seek approval for alternative generic formulations of the reference drug. Teva has a legal interest in accelerating FDA approval and launch of the products in each of its ANDAs. Teva offered unchallenged evidence that the product described in the GATE ANDA **[confidential information deleted]**.

There can be no doubt that the delay in obtaining FDA approval for **[confidential information deleted]** is an actual concrete injury, even if Teva's **[confidential information deleted]** donepezil formulations might not face the same delay.

This Court ruled in *Caraco* that suffering restraint from "the free exploitation of non-infringing goods" was sufficient injury to support standing. *Caraco*, 527 F.3d at 1292. Teva contends that the product described in the GATE ANDA does not infringe any valid and enforceable patent listed by Eisai in the Orange Book. That contention remain a live subject of controversy (in contrast to the situation in *Janssen*). Clearly there is standing to seek redress for this injury.

G. TEVA'S SHARED EXCLUSIVITY WITH RANBAXY WITH RESPECT TO ITS FIRST ANDA DOES NOT PRECLUDE JURISDICTION TO SEEK A DECLARATION THAT THE PRODUCT IN THE GATE ANDA DOES NOT INFRINGE THE DJ PATENTS.

Finally, the District Court relied on the fact that the FDA cannot approve the GATE ANDA until Teva's own 180–day exclusivity period passes and that the preliminary injunction precludes Teva from launching until Eisai's compound patent expires. (A21) But this does not affect the Article III analysis.

First, Teva is actively seeking to trigger its own exclusivity *before* the expiration of the compound patent by pressing its defense that the compound patent is unenforceable. If it can prevail on the merits of this defense, then its exclusivity period may well commence before expiration by the sale of a single unit of the product in the Teva ANDA. Caraco was in the same position. It could not profit from its challenge to the later-expiring patent until it succeeded in its litigation on the compound patent or that patent expired.

Second, even if Teva is unable to prevail in its litigation on Eisai's compound patent before that patent expires, a live controversy on the DJ Patents will continue to exist. The expiration of Eisai's compound patent will not trigger Ranbaxy's exclusivity with respect to the DJ Patents. In the

absence of a judgment as to the DJ Patents, only Ranbaxy's commencement of commercial sales of its product can trigger Ranbaxy's exclusivity.

It is far from certain that Ranbaxy will be able to launch upon the expiration of the compound patent. As noted above, Ranbaxy has run into serious difficulties with the FDA. The FDA has apparently concluded that at least certain of its manufacturing facilities failed to comply with standards for good manufacturing practices and that Ranbaxy had submitted untrue statements of facts in certain ANDA applications. Either circumstance could prevent final approval of its donepezil ANDA.

Moreover, Ranbaxy still faces potential liability under the two DJ Patents that Eisai has not disclaimed. That Eisai did not sue Ranbaxy under 35 U.S.C. §271(e) for infringing those patents does not preclude Eisai from bringing suit against Ranbaxy under 35 U.S.C. §271(a) for an injunction as the expiration date for the compound patent approaches. If Eisai succeeds in obtaining a preliminary injunction, Ranbaxy's launch — and therefore the commencement of its exclusivity period — may be delayed indefinitely. Eisai has every incentive to bring suit both to delay competition from Ranbaxy and to keep the product described in Teva's GATE ANDA blocked behind Ranbaxy.

Unlike Ranbaxy, Teva faces no exposure under the two non-disclaimed DJ Patents because of Eisai's covenant not to sue. Accordingly, Teva's shared exclusivity does not present the same obstacle to the product in the GATE ANDA that Ranbaxy's exclusivity presents. Accordingly, Teva's exclusivity with respect to the product in its first ANDA does not negate its standing to seek a declaration of non-infringement as to the DJ Patents in support of the GATE ANDA.

III. THE DISTRICT COURT ERRED IN DECLINING TO HEAR APPELLANTS' CIVIL ACTION TO OBTAIN PATENT CERTAINTY.

The District Court ruled in the alternative that if there were subject matter jurisdiction to hear Teva's civil action to obtain patent certainty as to the DJ Patents, the court would exercise the discretion extended to district courts under the Declaratory Judgment Act to decline to resolve that action. (A24) The court referred broadly to the reasons advanced to support its Article III ruling, but offered no other explanation for its ruling.

This determination was incorrect for two reasons. First, as a matter of law, district courts lack the discretion to decline jurisdiction over civil actions to obtain patent certainty. On the contrary, 35 U.S.C. §271(e)(5) states that district courts "shall" have jurisdiction over such claims.

Second, even if the District Court had discretion to decline jurisdiction, the District Court abused its discretion by declining to hear this case.

A. THE HATCH-WAXMAN ACT DOES NOT GIVE DISTRICT COURTS DISCRETION TO DECLINE TO HEAR CIVIL ACTIONS TO OBTAIN PATENT CERTAINTY IF THERE IS JURISDICTION UNDER ARTICLE III.

As the Supreme Court noted in *MedImmune*, the Declaratory Judgment Act provides that district courts "may" declare the rights of parties, not that they "must" do so. 127 S. Ct. at 776. Accordingly, courts have held that the Declaratory Judgment Act gives district courts the discretion to decline to resolve a declaratory judgment action even if there is subject matter jurisdiction under Article III. *Id.*; *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995).

However, what Congress gives, it can also take away and, in civil actions seeking patent certainty under the Hatch-Waxman Act, Congress has eliminated any discretion to decline jurisdiction. The MMA provides that where a patentee has not brought an infringement action within 45 days after the submission of an ANDA application with a Paragraph IV certification "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) "[T]he word 'shall' is ordinarily the language of command" and "militates against an implicit exception." *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001). Congress required district courts to entertain such suits under §271(e)(5) "to the extent consistent with the Constitution."[16]

The legislative history confirms that Congress intended to require district courts to resolve civil actions to obtain patent certainty so long as Article III jurisdiction was present. During the Senate debate on those portions of the MMA addressing the civil action to obtain patent certainty, Senator Kennedy said that the amendment clarified "a generic applicant's *right* to bring a declaratory judgment action" and noted that this "*right*" was "crucial to ensuring prompt resolution of patent issues." 149 Cong. Rec. S15885 (Nov. 25, 2003) (emphasis added). During the same debate, Senator McCain asked Senator Kennedy to explain "the purpose of the provision ... that amends Title 35 to say that courts *must* hear declaratory judgment actions brought by generic applicants." *Id.* (emphasis added). In replying, Senator Kennedy confirmed that "Federal district courts *are to entertain*

---

[16] Congress has the power to supersede prudential limitations on federal subject matter jurisdiction. *See Bennett v. Spear*, 520 U.S. 154, 162 (1997).

such suits for declaratory judgments so long as there is a 'case or controversy' under Article III of the Constitution."[17] *Id.* (emphasis added).

The legislative history also explains why Congress mandated the exercise of subject matter jurisdiction "to the extent consistent with the Constitution." The Hatch-Waxman Act gave patentees the *right* to initiate the resolution of patent disputes triggered by the submission of a Paragraph IV certification. There is no question that a district court has no discretion to decline to hear a patent infringement action brought under 35 U.S.C. §271(e)(4). By creating the civil action to obtain patent certainty, Congress sought to "level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if neither the patent owner nor the brand drug company brings suit within 45 days after receiving notice of the patent challenge." 149 Cong. Rec. S15885. If district courts were free to decline the efforts of generic companies to resolve the patent disputes that affect the timing of the approval and launch of generic drugs but obligated to

---

[17] This Court has relied on Sen. Kennedy's comments as an authoritative guide to interpreting the MMA's creation of a civil action to obtain patent certainty. *See Teva v. Novartis*, 482 F.3d at 1342-44.

hear infringement suits brought by patentees, the playing field would hardly be level.

Congress directed district courts to hear civil actions to obtain patent certainty "to the extent consistent with the Constitution." As demonstrated above, there was jurisdiction under Article III to consider Teva's claim as to the DJ Patents. The District Court had no discretion to decline to exercise that jurisdiction.

B. EVEN IF THERE WERE DISCRETION TO DECLINE JURISDICTION, THE DISTRICT COURT ABUSED ITS DISCRETION IN DISMISSING TEVA'S CLAIM.

This Court has emphasized that the discretion to decline to exercise subject matter jurisdiction in cases seeking a declaration of invalidity, unenforceability and/or non-infringement is limited and must be exercised in light of the importance of declaratory judgment actions under federal law.

In *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352 (Fed. Cir. 2004), a company faced with veiled threats of patent infringement litigation brought a declaratory judgment action seeking a declaration of non-infringement. The patentee subsequently brought a separate action in another district for patent infringement. The district court in the declaratory judgment action dismissed the claim as a matter of discretion.

This Court reversed. First, the Court found that the declaratory judgment claim was justiciable under Article III. Second, it found that the district court had abused its discretion in declining to hear the claim. The Court stressed that the Declaratory Judgment Act was enacted in large measure to address the plight of persons unable to obtain a resolution of real-world patent disputes because of the patentee's refusal to bring suit. *See id.* at 1358; *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988). The Court recognized that declaratory judgment actions serve important remedial purposes. "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." 387 F.3d at 1357 (*quoting Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993)); *accord SanDisk*, 480 F.3d at 1383.

In exercising discretion whether to exercise jurisdiction over a declaratory judgment action, "a court must determine whether resolving the case serves the objectives for which the Declaratory Judgment Act was created." *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871, 883 (Fed. Cir. 2008) (*citing Capo*, 387 F.3d at 1355)). Where, as here, the action is brought under the authority of the provisions of the MMA creating the civil

action to obtain patent certainty, the objectives of that legislation also play a critical role in the analysis.

As noted above, Congress' goal in creating the civil action to obtain patent certainty was to "level the playing field" by giving generic drug companies the same right as brand drug companies to initiate litigation to resolve the patent issues that affect the timing of generic launch. As this Court recognized in *Caraco*, Congress made the timing of generic launch turn on the existence of *judgments* of non-liability, and not simply on the fact of non-liability. Resolving Teva's complaint for a *judgment* of non-infringement therefore advances Congress' goal of accelerating the introduction of generic drugs consistent with the *legitimate* rights of pharmaceutical patentees.

The typical case in which district courts decline jurisdiction over declaratory judgment actions is where the action is duplicative of litigation addressing the same issues. *E.g., Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). This Court has also recognized that the pendency of reexamination proceedings may warrant declining jurisdiction. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1289 (Fed. Cir. 2007). No comparable circumstance is present here.

The paramount consideration in this case is that Eisai has attempted to forestall generic competition by strategically disclaiming and covenanting not to sue on patents of lesser importance in order to delay generic competition as long as possible. Congress has concluded that generic companies should be able to obtain judgments on those patents promptly so that the legislative scheme fashioned by Congress to accelerate the introduction of generic drugs can operate as intended. Accordingly, resolving this case would advance the goals of the MMA's creation of civil actions to obtain patent certainty.

The District Court in this case failed to offer a principled explanation for the exercise of its discretion to decline jurisdiction. The court referred broadly to the reasons that it gave for finding no Article III jurisdiction, but those reasons are irrelevant to the question whether, if Article III jurisdiction is present, the court should nevertheless dismiss the case. A district court is only called upon to exercise discretion if there is Article III jurisdiction. The District Court appeared to take the view that if this Court disagreed with its Article III ruling — as it should — it wanted to impose an additional obstacle to Teva's obtaining a judgment that would give it a chance to accelerate FDA final approval of the GATE ANDA. (A24) This is not a

proper basis for the exercise of discretion. *See SanDisk*, 480 F.3d at 1383. No other basis appears.

CONCLUSION

For the reasons set forth in this brief, this Court should reverse the judgment of the District Court dismissing the action seeking patent certainty with respect to the product described in the GATE ANDA and remand for further proceedings.

Respectfully submitted,

Henry C. Dinger

Francis C. Lynch
Henry C. Dinger, P.C.
Laurie S. Gill
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

Counsel for Teva Pharmaceuticals USA, Inc.

November 30, 2009