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.

REPLY BRIEF FOR PLAINTIFF-APPELLANT

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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.
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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:

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INTRODUCTION

In its opening brief, appellants (collectively "Teva") demonstrated that the dismissal of their complaint for declaratory relief for lack of subject matter jurisdiction cannot be squared with *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). Nothing in the brief of appellees (collectively "Eisai") supports a different conclusion because Eisai's attempts to distinguish *Caraco* are unpersuasive. For example, Eisai argues that Teva, unlike Caraco, was preliminary enjoined from launching a generic donepezil product in a case involving another patent. But Caraco faced a similar obstacle to its launching a generic product because of the statutory stay of FDA final approval.

Eisai improperly attempts to argue that Teva faces greater uncertainty than Caraco did because Teva's legal position is weak in that other case. Teva strenuously disagrees with this assessment. But even if it were true — and that question is not before this Court and there is no record here to permit the Court to resolve it — it does not distinguish *Caraco*. If anything, the generic company in *Caraco* faced an even greater burden than Teva does here because it challenged a patent that this Court had *finally* judged to be valid in earlier litigation.

Eisai further notes that two of the DJ patents were disclaimed while all of the patents in *Caraco* were subject to covenants not to sue. But Eisai offers no coherent explanation why that distinction should matter for jurisdictional purposes. All that matters for purposes of applying *Caraco* is that both disclaimed patents and patents that the patentee promises not to enforce remain listed in the Orange Book and therefore stand as obstacles to FDA final approval of ANDAs in the absence of a judgment of non-infringement, invalidity or unenforceability.

Eisai also argues that if the DJ patents prevent Teva from getting final approval, despite Eisai's disclaimers and covenants not to sue, Teva has only itself to blame because several years ago Teva argued successfully in completely unrelated litigation that the FDA lacks legal authority to remove patents from the Orange Book at the request of the patent holder. That Eisai must make such a bizarre and irrelevant appeal to "poetic justice" to support its argument, clearly signals the lack of any real merit in its position.

Neither the District Court nor Eisai in its brief have identified any principled distinction between this case and *Caraco*. In failing to follow *Caraco*, the District Court erred as a matter of law and this Court should reverse the dismissal of Teva's civil action to obtain patent certainty.

ARGUMENT

I. There is no distinction between this case and *Caraco* that has any bearing on the question of subject matter jurisdiction.

Teva contends that the District Court's decision to dismiss Teva's claims for declaratory relief cannot be reconciled with this Court's decision in *Caraco*. In response, Eisai argues that the circumstances presented here are different from those in *Caraco* and that those differences warrant a different outcome. However, the distinctions that Eisai draws are either illusory or irrelevant.

A. That Teva has been preliminarily enjoined in a separate case does not make this case closer to *Janssen* than to *Caraco*.

In its opening brief, Teva demonstrated that the District Court's reliance on the preliminary injunction entered in the litigation concerning the '841 patent to distinguish this case from *Caraco* was incorrect because Caraco faced a similar obstacle (in addition to the first filer's 180-day exclusivity period) to launching. As Eisai admits, when Caraco sought declaratory relief, it, like Teva, was unable to obtain final FDA approval. The patentee, Forest, had sued Caraco under 35 U.S.C. §271(e)(2) for infringing the patent on the active ingredient within 45 days of receiving notice of Caraco's challenge to that patent and thus obtained a stay of FDA approval for two and a half years under 21 U.S.C. §355(j)(5)(B)(iii). In

practical effect, that stay was very similar to a preliminary injunction. It did not resolve the case on the merits and was subject to immediate termination upon a judgment favorable to the generic challenger. In both respects, the stay and the preliminary injunction are quite different from the stipulated judgment in *Janssen Phamaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), which constituted a final resolution on the merits.

Eisai's only response is to attempt to blur the difference between a preliminary injunction and a final resolution on the merits in this case, by arguing the merits of Teva's defense in the separate case involving Eisai's '841 patent. According to Eisai, the preliminary injunction entered against Teva should be treated as tantamount to a final judgment on the merits (and thus similar to *Janssen*) because Teva's defense to Eisai's infringement claim lacks merit.

This is an improper argument because the merits of that defense are not before this Court. The preliminary injunction was granted in an entirely separate case on a record that is not before this Court. Eisai should have heeded the cases that Eisai cites for the proposition that reference to "extra-record evidence" is improper. Eisai Br. at 42.

Moreover, Eisai's attempts to draw negative inferences from Teva's conduct of that litigation are without merit. For example, Eisai argues that

Teva abandoned its obviousness defense and asserted its inequitable conduct defense more than a year after the litigation commenced. However, given the heightened pleading requirements for inequitable conduct and the obvious fact that much evidence of deceptive intent will be in the possession of the patentee, it was entirely proper for Teva to wait until it had reviewed Eisai's documents and investigated its practices regarding co-pending patent applications before asserting inequitable conduct. The District Court agreed and rejected Eisai's argument that Teva's motion to amend was untimely.

In the same vein, Eisai argues that Teva conceded validity by abandoning its obviousness defense. But Teva only abandoned that defense because, in light of what it perceived to be a strong inequitable conduct defense, it sought to simplify the case to bring it to trial as quickly as possible. Unfortunately, Eisai's resistance to discovery and dilatory motion practice in the case on the '841 patent has largely thwarted Teva's efforts to bring the case to trial quickly.[1]

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[1] *See* p. 13 n.2 *infra*. Eisai compounds the impropriety of relying on extra-record material from the litigation over the '841 patent by urging that this Court infer the weakness of Teva's defense from Teva's decision not to appeal the grant of the preliminary injunction. No such inference is permissible because the reason for Teva's decision not to appeal does not appear in the record. In fact, Teva chose not to appeal for the same reason that it withdrew its obviousness defense. The '841 patent expires in late 2010. Teva recognized that an immediate appeal of

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But even if it were permissible to consider Eisai's improper speculation and innuendo, Eisai's argument once again fails to distinguish *Caraco*. If anything, Caraco faced even longer odds than Teva does here even under Eisai's unsupported and egregiously slanted description of Teva's case. For a declaratory judgment to do Caraco any good, Caraco had to prevail on Forest's claim that the product in Caraco's ANDA infringed the '712 patent, which claimed the active ingredient of Caraco's generic drug, escitalopram. To prevail, Caraco had to establish that that patent was invalid because the law required Caraco to use the same active ingredient as the reference drug and so Caraco had no plausible non-infringement position. But Forest had already litigated the validity of the '712 patent and this Court affirmed a judgment that that patent was not invalid. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). As Judge Friedman (under)stated in his *Caraco* dissent, "Caraco's argument assumes that it will prevail in its non-infringement claim — an uncertain assumption at best." 527 F.3d at 1298 (Friedman, J., dissenting).

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the preliminary injunction would likely eliminate any chance of obtaining a final decision on the merits of its defense before the expiration of that patent. Accordingly, Teva chose to move as expeditiously as possible to trial on the merits on its inequitable conduct defense.

Thus, even if Eisai's *ipse dixit* concerning Teva's prospects on the merits of its defense in the case on the '841 patent were correct — and there is absolutely no basis on this record to assume that — the prospect of Caraco's persuading a district court to invalidate a patent found not invalid in a judgment affirmed by this Court on the merits in a precedential opinion was no more promising. Eisai makes no argument to the contrary.

Nor would such an argument have any legal significance. This Court in *Caraco* recognized that efforts like Eisai's to handicap the declaratory judgment plaintiff's prospects on the merits are irrelevant to the Article III analysis. In response to Judge Friedman's observation about Caraco's highly uncertain prospects on the merits, the Court ruled that "[a] plaintiff need not prove it will prevail on the merits of its case in order to prove that it has standing to bring the case." *Id.* at 1295 n.14. It is only under circumstances such as those in *Janssen*, where the declaratory judgment plaintiff has *finally* lost on the merits that a relevant line is crossed. This case, like *Caraco*, falls short of that line.

B. As in *Caraco*, Teva's injury-in-fact is traceable to Eisai.

Eisai argues that this case is distinguishable from *Caraco* because Teva could have challenged the '841 and the DJ patents with respect to the GATE ANDA sooner than it (and Ranbaxy) did. Eisai Br. at 32-33. Had it

done so, Teva would have enjoyed "first filer" status as to the GATE ANDA and thus avoided its current need to trigger Ranbaxy's exclusivity by obtaining a declaratory judgment. From this Eisai argues that the injury-in-fact on which Teva predicates Article III standing — the inability to launch the GATE ANDA product until the expiration of Ranbaxy's exclusivity period — is attributable to Teva's own conduct.

Initially, this argument does not distinguish *Caraco* at all. Had Caraco prepared and filed its ANDA with greater dispatch, it could have been the first filer itself, or at least have shared exclusivity with the first filer. Yet nothing in *Caraco* even hints that such considerations affected the justiciability analysis. Jurisdiction does not turn on a race to the FDA by competing generic drug companies.

Eisai relies on non-ANDA cases in which the court found no standing under Article III because the plaintiff voluntarily took action that was inconsistent with the asserted cause of action. Thus, in *Taylor v. FDIC*, 132 F.3d 753, 767 (D.C. Cir. 1997), the court ruled that a plaintiff lacked standing to sue his government employer to seek reinstatement where he had voluntarily resigned from his job. (The court had rejected the plaintiff's constructive discharge argument.) Because of the resignation, the harm for

which plaintiff sought redress was not "fairly traceable" to the defendant's conduct, as required by Article III. *Id.*

Similarly, in *Bhd. of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006), a union lacked standing to sue to enforce its collective bargaining rights in circumstances where they had knowingly agreed to contract terms that denied bargaining rights in those circumstances. Under those circumstances, the loss of bargaining rights was not "fairly traceable" to the defendant's conduct. In *Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc.*, 454 F. Supp. 2d 62, 71 (E.D.N.Y. 2006), the plaintiff was denied standing to challenge as antitrust violations the terms of a supply contract that it had refused to sign. In *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976), the Court denied standing to a state that challenged an unconstitutional tax imposed by another state on the plaintiff state's residents. The Court ruled that while the non-resident taxpayers had standing to challenge the tax, another state did not because the ostensible loss of revenue resulted from the plaintiff state's affirmative extension of a tax exemption to its residents for taxes paid to another state. *Id.* at 664. In each of these cases, the court found that the plaintiff's affirmative conduct broke the causal link between the challenged conduct and the harm for which plaintiff sought redress.

Caraco precludes Eisai's argument here. In this context, Teva's harm is fairly traceable to Eisai's conduct as a matter of law. In *Caraco*, this Court ruled that a brand company's listing of patents in the Orange Book "effectively denies Caraco an economic opportunity to enter the marketplace" if the ANDA applicant cannot obtain a judgment as to the listed patents. 527 F.3d at 1292-93. "It is well-established that the creation of such barriers to compete satisfies the causation requirement of Article III standing." *Id.* at 1293. It mattered not at all that Caraco's harm was in some sense the result of its failing to submit its Paragraph IV certification sooner than Ivax did. Teva's harm is likewise fairly traceable to Eisai's listing patents in the Orange Book that it decided not to enforce.

C. That Teva has final FDA approval to sell one generic donepezil formulation does not deprive it of standing to seek a declaratory judgment to accelerate final approval for an alternative formulation.

Echoing the District Court, Eisai attempts to distinguish *Caraco* by noting that Teva, unlike Caraco, has final FDA approval to launch the generic donepezil formulation described in its first ANDA, even if FDA approval of the formulation described in the GATE ANDA is delayed until Ranbaxy launches its donepezil product or Teva obtains the declaratory judgment it seeks. However, as Teva explained in its opening brief, the GATE formulation is different from the earlier one, and offers commercial

advantages to Teva that it has every right to pursue. As to the GATE formulation, Teva claims that it is suffering restraint from "the free exploitation of non-infringing goods" and that, under *Caraco*, is a sufficient injury to establish standing under Article III. *See* 527 F.3d at 1291.

Eisai does not dispute that Teva alleged such an injury or that this Court in *Caraco* viewed such an injury as sufficient to support standing under Article III. Its only response is to suggest that Teva could avoid the injury without a declaratory judgment by selling the generic product in its first ANDA and then selectively waiving its exclusivity as first filer in favor of the product described in the GATE ANDA. Eisai Br. at 31-32.

Initially, Eisai cites no statute, regulation or case establishing its assertion about selective waiver. Instead it relies primarily on the FDA's 2004 response to a citizen's petition in which the FDA took the position that relinquishment or waiver of the statutory 180-day exclusivity was permissible. (A461-473) Courts have not yet ruled on this point. The closest judicial decision appears to be *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997), in which the court denied a preliminary injunction that was sought to prevent FDA approval of a selective waiver. But neither this Court nor the D.C. Circuit have considered the issue, particularly in a shared exclusivity context.

Moreover, the "selective waiver" alternative that Eisai invokes is itself not without risk. If Teva were to launch the product described in its first ANDA "at risk" (*i.e.*, before patent invalidation or expiration) to permit a selective waiver in favor of the GATE ANDA, it would face possible liability for patent infringement, as to both the first ANDA product and the GATE ANDA product. As the Supreme Court has emphasized, the point of allowing declaratory judgment actions is to permit a potential defendant to get a resolution of legal issues without the need to "bet the farm, so to speak, by taking ... violative action." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007).

But even if the selective waiver placed the party receiving the waiver in the shoes of the party granting it for all purposes, such a selective waiver in favor of the GATE ANDA would avoid the need for a declaratory judgment only if Teva can sell the product in its first ANDA before the '841 patent expires in November 2010. If that patent expires before Eisai's infringement claim under 35 U.S.C. §271(e)(2) is resolved, that claim will become moot. Under those circumstances, Teva will lose its exclusivity rights because the FDA will require Teva to change its Paragraph IV certification as to the '841 patent to a Paragraph II certification (*i.e.*, that the patent has expired) under 21 U.S.C. §355(j)(2)(A)(vii)(II). *See Mylan Labs.,*

Inc. v. Thompson, 389 F.3d 1272, 1282-84 (D.C. Cir. 2004). While Teva remains hopeful that it can proceed to trial and prevail on Eisai's infringement claim under the '841 patent between now and November, Eisai's dilatory tactics in that litigation make that an increasingly uncertain prospect.[2]

The expiration of the '841 patent may moot the litigation over *that* patent, but will not moot Teva's claims directed at the DJ patents. This is because even after the '841 patent expires, Teva will not be able to launch its GATE product until Ranbaxy's 180-day exclusivity period also expires. Absent a judgment of invalidity, unenforceability or non-infringement as to the DJ patents, the only event that will trigger Ranbaxy's exclusivity will be Ranbaxy's launching its product. Specific objective circumstances make such a launch upon the expiration of the '841 patent most unlikely.

First, while Eisai has covenanted not to enforce *against Teva* the two DJ patents it has not disclaimed, Ranbaxy enjoys no such insulation against

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[2] Eisai's dilatory motion practice delayed discovery on Teva's inequitable conduct defense for more than a year. *Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, 629 F. Supp. 2d 416 (D.N.J. 2009). Notwithstanding this ruling by the District Court that pattern of conduct evidence was relevant, Eisai filed a further opposition to Teva's renewed motion for discovery on pattern of conduct, which the magistrate judge allowed, forcing another appeal to the District Court, which appeal is currently pending. No trial date has been scheduled.

liability. Eisai dismisses as "wild accusation" the suggestion that, as the '841 patent nears expiration in November 2010, Eisai will attempt to enforce those two patents against Ranbaxy. But there is nothing "wild" about it. It is manifestly in Eisai's economic interest to take all available steps to delay generic competition as long as possible since Eisai generates hundreds of millions of dollars in sales of its donepezil product *each month*. It is Eisai's suggestion that it might not sue Ranbaxy that lacks credibility. And for all its ranting about Teva's suggestion that Eisai will sue Ranbaxy to prevent Ranbaxy's launch, Eisai neither denies that it will bring such a suit nor offers a covenant not to sue Ranbaxy.

Nor should Eisai's promise not to enforce those two patents against Teva suggest any lack of interest in enforcing those patents. It costs Eisai little to make such a promise to Teva so long as it could enforce those patents against Ranbaxy since Teva cannot launch its GATE product until Ranbaxy launches or it obtains a final court decision on the DJ patents. 21 U.S.C. §355(j)(5)(B)(iv) (old)[3]; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §1102(b)(3), 117 Stat.

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[3] As demonstrated in Teva's opening brief, the timing of FDA approval of Teva's ANDA is governed by the provisions of the Hatch-Waxman Act in force before the Medicare Modernization Act of 2003. The pertinent

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2066 (2003). As this Court recognized in *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007) and *Caraco*, Congress created the civil action to obtain patent certainty in 21 U.S.C. §355(j)(5)(C) to allow non-first filers to obtain a judgment where the brand company seeks to avoid litigation that might accelerate generic competition.

The real prospect that Eisai will seek to delay Ranbaxy's launch with patent litigation is not the only obstacle to such launch. Official FDA documents published at its website disclose the existence of such extensive quality control problems at Ranbaxy's facilities, both in India and the United States, that it is very doubtful that the FDA will give final approval to Ranbaxy's donepezil ANDA when the '841 patent expires later this year. In 2006 and in 2008, FDA sent formal warning letters to Ranbaxy identifying extensive quality control and documentation deficiencies in two different manufacturing facilities in India.[4] In the 2006 FDA Letter, the FDA warned

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pre-MMA provisions are set forth in Addendum B to Teva's opening brief, and are cited as "21 U.S.C. §___ (old)."

[4] Warning letter dated June 15, 2006 from FDA to Ranbaxy Labs. Ltd. (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075947.htm) (last visited Mar. 1, 2010) ("2006 FDA Letter"); warning letter dated Sept. 16 2008 from FDA to Ranbaxy Labs. Ltd. (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048133.htm) (last visited Mar. 1, 2010) ("2008 FDA Letter I");

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Ranbaxy that until the agency "has confirmed correction of the deficiencies observed during the most recent inspection and compliance with CGMPs [Current Good Manufacturing Practice Regulations], this office will recommend withholding approval of any new applications listing your Paonta Sahib facility as the manufacturer of finished pharmaceutical drug products." FDA also threatened to deny entry of articles manufactured by Ranbaxy as authorized by 21 U.S.C. § 381(a)(3). 2006 FDA Letter. Two years later, Ranbaxy's problems had not been resolved and the FDA sent another warning letter reporting "indications of continuing, systemic CGMP deficiencies at the Paonta Sahib facility." 2008 FDA Letter I.

In fact, FDA's concerns had expanded to include an additional Ranbaxy manufacturing facility in India. After reciting extensive deficiencies observed by FDA inspectors, FDA informed Ranbaxy that "[u]ntil all corrections have been completed and FDA can confirm your firm's compliance with CGMPs, this office will recommend disapproval of *any* new applications or supplements listing your firm as a manufacturing location of finished dosage forms and active pharmaceutical ingredients."

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warning letter dated Sept. 16, 2008 from FDA to Ranbaxy Labs. Ltd. (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048134.htm) (last visited Mar. 1, 2010) ("2008 FDA Letter II").

2008 FDA Letter II (emphasis added). This statement on its face applies to all Ranbaxy manufacturing facilities. Again, the FDA raised the prospect of refusing admission to the U.S. of products made by Ranbaxy. *Id.*

Ranbaxy's difficulties with the FDA continue to worsen. On December 21, 2009, the FDA sent yet another warning letter, this time to Ranbaxy's American subsidiary concerning a manufacturing facility in the U.S.[5] The concluding substantive paragraph of the letter revealed the systemic scope of Ranbaxy's problems:

> Finally, we note that the CGMP violations listed in this letter include similar violations to those cited in the June 2006 and September 2008 Warning Letters issued to other Ranbaxy Laboratories facilities (i.e., the corporation). *It is apparent that Ranbaxy's attempts to make global corrections after past regulatory actions by the FDA have been inadequate.* We remind you that Ranbaxy is responsible for ensuring that all Ranbaxy drug manufacturing operations comply with applicable US requirements, including the CGMP regulations. FDA expects Ranbaxy immediately to undertake a comprehensive assessment of its global manufacturing operations to ensure that all sites manufacturing drug for the US market conform to US requirements.

2009 FDA Letter (emphasis added).

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[5] Warning letter dated Dec. 21, 2009 from FDA to Ohm Labs., Inc. (available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm199027.htm) (last visited Mar. 1, 2010) ("2009 FDA Letter").

Eisai does not dispute that Ranbaxy faces serious regulatory problems. Rather it attempts to avoid any consideration of those problems. First, it argues that Teva improperly relies on materials that lie outside the record in this case. However, in stark contrast to the extra-record materials on which Eisai relies, Teva relies on the official documents of a federal governmental agency published on the FDA website, matters on which federal courts routinely take judicial notice. *See, e.g., Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 n.3 (Fed. Cir 1990); *Denius v. Dunlap*, 330 F.3d 919, 926-27 (7th Cir. 2003); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003). Moreover, the most significant of the documents on which Teva relies, the 2009 FDA Letter, did not become publicly available until very recently, well after Teva submitted its opening brief to this Court.[6]

Second, Eisai suggests that Ranbaxy's troubles are irrelevant because donepezil is not on the FDA's list of drugs manufactured at the Indian

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[6] The issue here does not turn on the accuracy of the FDA's characterization of the conditions in Ranbaxy's facilities. So long as the FDA believes that there are systemic problems in Ranbaxy's facilities — and on that point the warning letters are perfectly clear — then Ranbaxy will face considerable difficulty in getting new products approved by the FDA. It is the likely delay in FDA approval, coupled with the additional likelihood of Eisai's pursuing further patent litigation against Ranbaxy,

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facilities that failed FDA inspection. Eisai Br. at 42 (citing http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118441.htm). But the list referenced by Eisai is a list of *approved* drugs.[7] Since FDA has not finally approved Ranbaxy's sale of generic donepezil, it is not surprising that donepezil is not on the list. Ranbaxy could not currently sell donepezil in the U.S. even if its facilities had passed the FDA's inspections.

Third, Eisai argues that, as a matter of law, the mere possibility that Ranbaxy might not launch when the '841 patent expires is insufficient to support declaratory judgment jurisdiction, relying on *Janssen.* Eisai Br. at 43. However, in *Janssen*, Apotex pointed to nothing to suggest that Teva, the first filer, would not launch its generic product immediately upon the expiration of the patent covering the active ingredient. This Court noted: "At no time between the filing of the counterclaims through the final judgment was there any basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market in the future." 540 F.3d at

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that makes Teva's claims concerning the DJ patents justiciable even after the expiration of the '841 patent.

[7] Information concerning the final approval of Ranbaxy's ANDAs for each of the listed drugs is available at the FDA website: http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/.

1363. Here, by contrast Teva has identified two serious concrete obstacles to Ranbaxy's launching its generic donepezil product in November 2010: the two non-disclaimed DJ patents and FDA's systemic concerns with Ranbaxy's compliance with Current Good Manufacturing Practice Regulations. Thus, the likeliest conclusion here is that Ranbaxy will not launch its product immediately upon the expiration of the '841 patent and will not be in a position to launch for a considerable period thereafter. Under these circumstances, there is subject matter jurisdiction over Teva's claim for declaratory relief to trigger Ranbaxy's exclusivity.

D. There is no basis to distinguish disclaimed patents from patents subject to a covenant not to sue for jurisdictional purposes since neither disclaimers nor covenants not to sue remove such patents from the Orange Book.

Eisai argues that even if there is subject matter jurisdiction over Teva's claim that the two DJ patents as to which Eisai covenanted not to sue are invalid or not infringed, a different result should obtain as to the two DJ patents that Eisai dedicated to the public under 35 U.S.C. §253. Eisai never explains, however, *why* the disclaimed patents should be treated differently, and no reason is apparent.

Eisai states that courts "universally" find no jurisdiction to resolve disputes concerning disclaimed patents. Eisai Br. at 44. While this is often

the case, it is also true as to patents as to which the patentee has covenanted not to sue. As a result of the disclaimer or covenant, infringement disputes typically become moot. *See Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed. Cir. 1991) (covenant not to sue moots infringement claim against the party to which covenant granted); *National Semiconductor Corp. v. Linear Tech. Corp.*, 703 F. Supp. 845, 850 (N.D. Cal. 1988) (disclaimer of patent moots controversy whether patent infringed). In such situations, the covenant or the disclaimer typically removes the legal obstacle to the accused infringer's intended activities and eliminates any concrete stake the parties have in the resolution of the dispute.

Courts have recognized circumstances, however, where even though the accused or would-be infringer no longer faces infringement liability, there are other practical consequences that turn on the resolution of legal questions concerning the disclaimed patent or the patent covered by a covenant not to sue. For example, in *National Semiconductor*, the patentee (like Eisai here), faced with litigation challenging its patent, elected to disclaim the patent. The district court recognized that the disclaimer mooted any issue as to whether the accused infringer's product infringed the patent. *National Semiconductor*, 703 F. Supp. at 850. However, the accused

infringer had counterclaimed, alleging that the patent was invalid and inequitably procured and that that the inequitable procurement of that invalid patent supported antitrust and unfair competition claims. The district court ruled that that invalidity issue was not, therefore, moot and that the court had jurisdiction to resolve it. *Id.* at 850-51.

Similarly, in *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 2005), a jury returned a verdict in a patent case that the patent was not invalid but also that it was not infringed by the defendant's product. The patentee sought to avoid any further scrutiny of the validity of the patent or its conduct in procuring it by giving the victorious defendant a covenant not to sue. This Court ruled that the covenant did not moot the defendant's invalidity and inequitable conduct counterclaims. *Id.* at 1347-49; *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993) (party seeking a declaration of invalidity has standing to pursue that challenge even after a finding of non-infringement).

Caraco identified another situation in which a patent retained practical legal significance notwithstanding action by the patentee that insulated the challenger from any infringement liability. It is the situation we face in this case, *i.e.,* where the patent is listed in the Orange Book and thereby prevents a generic company from launching its product because the

Hatch-Waxman Act makes the timing of FDA approval of a non-first filer's ANDA turn on the existence of a *final court decision* of invalidity or non-infringement of the patents listed in the Orange Book, not simply on the absence of liability for infringing the patent. 21 U.S.C. §355(j)(5)(B)(iv) (old); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §1102(b)(3), 117 Stat. 2066 (2003). Because the statute invests the existence of a final court decision with practical and legal significance, and because neither a covenant not to sue nor a disclaimer of a patent eliminates the importance of obtaining such a decision, Teva's claims as to the DJ patents are not moot.[8]

Eisai has no answer to this, so it resorts to empty rhetoric. Eisai insists that it has no incentive to "commit the substantial resources entailed in patent litigation to submit Teva's claims to adversarial testing." Eisai Br. at 47. But Teva's DJ claims require no such commitment of substantial resources to litigate. As this Court noted in *Caraco*, "it appears that if [the patentee] would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would

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[8] *Merck & Co., Inc. v. Apotex, Inc.*, 2007 WL 4082616 (D.N.J., Nov. 15, 2007), on which Eisai relies, does not warrant a contrary conclusion. It was decided before *Caraco* and failed to anticipate the reasoning of the Court in that case.

redress Caraco's alleged injury-in-fact just as well as any other court judgment." 527 F.3d at 1293 n.11. If, as Eisai would have this Court believe, it is indifferent to the disclaimed patents, it should have no difficulty agreeing to such a consent decree. Eisai's crocodile tears about litigation expense should not fool the Court.

Eisai also makes the outlandish suggestion that the continued listing of the four DJ patents in the Orange Book is somehow Teva's own fault because Teva was a party to litigation years ago in which the court found that the FDA lacked statutory authority to "de-list" patents as to which a Paragraph IV certification was made. *See* Eisai Br. at 46-47 (citing *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). Manifestly, the fact of Teva's participation in that litigation has no bearing on this case. Eisai's implicit suggestion that affirming the judgment here would satisfy some sense of poetic justice for Teva's past litigation efforts when an Orange Book listing was advantageous to it is so absurd that there is little wonder that Eisai does not spell it out.

All of the DJ patents remain listed in the Orange Book. All of them, therefore, sustain Ranbaxy's exclusivity. Although Ranbaxy will likely be in no position to enjoy that exclusivity for some time, that exclusivity blocks Teva and other generic companies from competing with Eisai. It will

continue to block FDA approval of Teva's GATE ANDA, even after the only patent that Eisai can still assert against Teva has expired. Under those circumstances, *Caraco* squarely holds that Teva can bring a declaratory judgment action to challenge the DJ patents. The judgment dismissing its claims must be reversed.

II. The District Court lacked discretionary power to decline subject matter jurisdiction and, even if it had such power, it was abused in this case.

A. By providing that district courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over civil actions to obtain patent certainty, Congress eliminated any discretion to decline jurisdiction over such actions.

Teva brought its claims as a "civil action to obtain patent certainty" under 21 U.S.C. §355(j)(5)(C). (A37) By statute, federal courts "*shall*, to the extent consistent with the Constitution, have subject matter jurisdiction" in any such action. 35 U.S.C. §271(e)(5) (emphasis added). By using "shall" — the "language of command," *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001) — Congress made clear that such claims fell into the class of claims that federal courts are generally obliged to resolve, so long as constitutional limits on subject matter and personal jurisdiction are met. As Teva demonstrated in its opening brief, the legislative history confirms this reading.

Eisai attempts to belittle Teva's textual argument by pointing out that the phrase "shall have … jurisdiction" is commonplace in the U.S. Code when Congress seeks to have federal courts resolve particular controversies. Eisai is certainly correct that the phrase is ubiquitous. All of the major statutory grants of federal jurisdiction employ it, including the jurisdiction to resolve patent disputes. *See, e.g.*, 28 U.S.C. §§ 1331-1340. But Eisai's argument overlooks the fact that *none* of these statutes creates any discretionary power on the part of federal courts to decline the jurisdiction that by statute the court "shall have." Eisai does not cite a single example of a statute that employs the phrase "shall have jurisdiction" that also gives the federal court the discretionary power to decline jurisdiction.

The federal Declaratory Judgment Act is a striking exception to the ubiquitous use of "shall have … jurisdiction." 28 U.S.C. §2201 provides that federal courts "may" declare the rights of litigants, and by using "may" instead of "shall" Congress allowed federal courts to decline jurisdiction over declaratory judgment actions in the sound exercise of their discretion. *MedImmune,* 549 U.S. at 136. Had Congress not added 35 U.S.C. §271(e)(5) as part of the 2003 amendment of the Hatch-Waxman Act, district courts would have discretion to decline jurisdiction over declaratory judgment actions brought by generic drug companies.

But Congress did pass that statute and thereby provided that federal courts "shall have jurisdiction" over such declaratory judgment actions, just as federal courts "shall have jurisdiction" over diversity cases, admiralty claims and patent infringement actions. When Congress says that federal courts "shall have jurisdiction," then, assuming other jurisdictional requirements are met (*e.g.*, amount in controversy, personal jurisdiction over the defendant), federal courts must exercise their judicial power when their jurisdiction is invoked.

Indeed, when it enacted §271(e)(5), Congress adopted an even broader and clearer mandate to exercise jurisdiction than in most other situations in which it provided that federal courts "shall have jurisdiction." Congress specified that federal courts "shall have" jurisdiction over civil actions to obtain patent certainty "*to the extent consistent with the Constitution.*" (emphasis added). In most settings, even if Congress has provided that federal courts "shall have jurisdiction," the Supreme Court has articulated certain "prudential" doctrines that limit subject matter jurisdiction. In *Bennett v. Spear*, 520 U.S. 154 (1997), for example, the Court considered the "prudential" limitation that the interest that the plaintiff seeks to enforce must be within "zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Id.* at 163

(quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). The Court recognized, however, that Congress can "abrogate" such prudential limits, and in *Bennett* the Court found that Congress had abrogated the non-constitutional "zone of interests" limitation on standing in the Endangered Species Act. *Id.* at 164-65.

Eisai observes that *Bennett* held that Congress must "expressly negate[]" prudential limits on jurisdiction for them to be abrogated, *id.* at 163, and argues that 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." Eisai Br. at 52. But the statute here *expressly* provides that district courts "shall have" jurisdiction "*to the extent consistent with the Constitution.*" (emphasis added). That the highlighted phrase "expressly negate[s]" non-constitutional limitations on jurisdiction is obvious.[9] What else could it mean? Eisai suggests no alternative meaning for that statutory phrase. It ignores it altogether.

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[9] *Bennett* did not require Congress to use any particular phrase to "expressly negate" a prudential limitation. In *Bennett*, the statute in question merely stated that "any person may commence a civil suit on his own behalf" to enforce the Endangered Species Act. 520 U.S. at 164 n.2. The statute did not read "any person, *including persons who fall outside the zone of interests protected by this act*, may commence ...."

Eisai also belittles the late Senator Kennedy's statements in the Congressional Record about the goals and purposes of the "civil action to obtain patent certainty." Eisai argues that Senator Kennedy's views on subject matter jurisdiction are "unilluminating" and in some instances failed to anticipate legal developments. Eisai Br. at 53-54 & n.9. But Teva cited his comments as legislative history, not as a treatise on federal subject matter jurisdiction. This Court has relied on these same statements to shed light on the goals Congress sought to achieve by enacting 35 U.S.C. §271(e)(5). *Teva*, 482 F.3d at 1343-44. It is clear from those comments that Congress sought to ensure that patent disputes concerning proposed generic drugs be resolved quickly, in parallel with FDA consideration of ANDAs, by giving generic companies the same *right* to seek the resolution of such disputes that brand companies were granted in 35 U.S.C. §271(e)(2).

The discretion for which Eisai argues not to resolve such disputes is thus squarely inconsistent with both the text and legislative history of §271(e)(5). Accordingly, if the Court concludes, as it should, that Teva's claim for a declaration as to the DJ patents is justiciable under Article III

(and therefore "consistent with the Constitution"), it must vacate the dismissal of Teva's claim for want of subject matter jurisdiction.[10]

B. Even if the District Court had discretion to decline jurisdiction, its discretion was abused in this case.

Teva explained in its opening brief why the District Court's decision to decline subject matter jurisdiction over Teva's civil action to obtain patent certainty constituted an abuse of discretion. The District Court failed to offer a principled explanation for its decision and failed to take into account the policy considerations that this Court and Congress have stressed in this context. Teva Br. at 45-49.

Eisai makes no substantive response to any of these arguments. In a single paragraph, Eisai simply suggests that the District Court "was well aware of the background facts and history of this action." Eisai Br. at 54-55. This kind of hand-waving response requires no reply.

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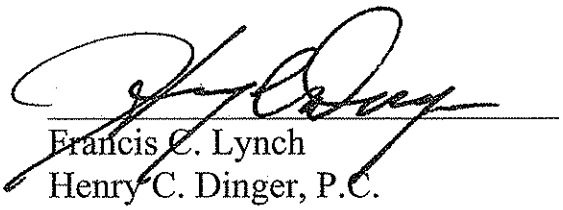
[10] Eisai appears to argue that even if there is subject matter jurisdiction, a declaratory judgment is an equitable remedy and that the district court has the discretion to decline relief "on the merits" if it finds it would be inequitable to do so. That issue is plainly not before this Court since the District Court did not reach the merits. The District Court's alternative ruling was plainly a decision to "decline jurisdiction" (A24), not to deny relief on the merits. Beyond that, the statutory direction that federal courts "shall … have jurisdiction" to declare the merits of patent disputes at the behest of generic companies as well as patentees should be read to require courts to reach the merits.

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,



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March 2, 2010

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.

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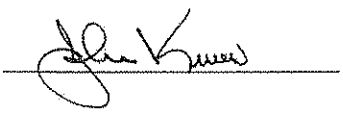
March 2, 2010



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DECLARATION OF AUTHORITY PURSUANT TO 28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)

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:

I am an employee of Counsel Press. Counsel Press was retained by Attorneys for Plaintiff-Appellant to print the enclosed documents.

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March 2, 2010

John C. Kruesi, Jr.

CERTIFICATE OF COMPLIANCE

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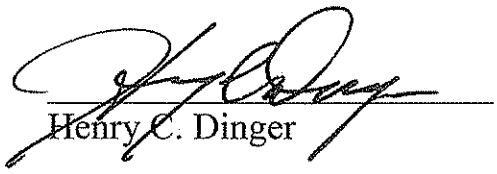

Henry C. Dinger

March 2, 2010