IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BONE CARE INTERNATIONAL LLC and GENZYME CORPORATION, Plaintiffs, v. SANDOZ INC., Defendant.	C.A. No.: 09-cv-524-GMS

DEFENDANT SANDOZ INC.'S MOTION FOR RECONSIDERATION OF THIS COURT'S SEPTEMBER 30, 2010 ORDER GRANTING-IN-PART GENZYME'S MOTION TO DISMISS SANDOZ'S DECLARATORY JUDGMENT COUNTERCLAIMS

Defendant Sandoz Inc. ("Sandoz") hereby moves for reconsideration by this Court of its September 30, 2010 Order (D.I. 29) granting-in-part Plaintiffs', Bone Care International, LLC and Genzyme Corp. (collectively, "Genzyme") motion to dismiss (D.I. 11) Sandoz's declaratory judgment counterclaim with respect to U.S. Patent No. 6,903,083 (the "'083 patent")[1] pursuant to D. Del. LR 7.1.5. and in support of its Motion, states as follows:

[1] Sandoz does not seek reconsideration of this Court's dismissal of Sandoz's counterclaim relating to U.S. Patent No. 5,707,980 (the "'980 patent"), which expired on August 17, 2008, but was incorrectly listed in the Orange Book as expiring on August 17, 2010, because it no longer blocks the FDA's approval of Sandoz's ANDA. *See Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282-83 (D.D.C. 2004) (paragraph IV certification converts to a paragraph II certification upon patent expiration).

I. INTRODUCTION

Sandoz bases its Motion on the grounds that there was a significant clarification or change in controlling law by (1) the Federal Circuit in *Teva Pharms. USA, Inc. v. Eisai Co.*, --- F.3d ----, 2010 WL 3895375, at *2 (Fed. Cir. Oct. 6, 2010) (attached as Exhibit A) (hereinafter, "*Eisai*") along with (2) the United States Court of Appeals for the D.C. Circuit's reversal of the FDA's application of the "delist rule" in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) (hereinafter, the "*Losartan Appeal*"). If the Court had the October 6, 2010 decision in *Eisai* before it, along with the decision in the *Losartan Appeal*, it likely would have concluded that Sandoz's declaratory judgment counterclaim relating to the '083 patent was justiciable under Article III. For these reasons, Sandoz respectfully requests that this Court grant its Motion.[2]

II. ARGUMENT

A. Based On A Change In Controlling Law Sandoz's Motion for Reconsideration is Proper

The purpose of a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." *Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). Accordingly, a court may alter or amend its judgment if the movant demonstrates at least one of the following: (1) a change in the controlling law; (2) availability of new evidence not available when the motion was granted; or (3) a need to correct a clear error of law or fact or to prevent manifest injustice. *See id.* (relying on *North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995)). Because the Court did not have the opportunity to

[2] To the extent District Court Local Rule 7.1.1. is applicable to this Motion, undersigned counsel advised counsel for Genzyme of the subject matter of this Motion, but agreement cannot be reached.

consider this case in view of *Eisai* and the *Losartan Appeal* when it ruled on Genzyme's Motion,[3] the Court's Order is premised on legal errors which, left unchanged, would result in a manifest injustice to Sandoz.

B. This Court Should Hear Sandoz's Declaratory Judgment Counterclaim Because Sandoz Has Realized A Cognizable "FDA-Approval-Blocking Injury" Under *Eisai*

This Court's dismissal of Sandoz's declaratory judgment counterclaim seeking adjudication of patent validity and non-infringement for the '083 patent is improper in view of controlling Federal Circuit law, decided last week. *See Eisai*, 2010 WL 3895375, at *2. Under facts similar to this case, the Federal Circuit held that the district court erred in dismissing declaratory judgment counterclaims where the second-filer would suffer "FDA-approval-blocking injury" – a legally cognizable injury-in-fact under Article III. *See id.* at *4, *6. Sandoz suffers the same injury-in-fact as in *Eisai*, and such injury is fairly traceable to Genzyme's listing of the '083 patent in the Orange Book. *Id.* at *6.

In *Eisai*, the brand company, Eisai Co., Ltd. ("Eisai"), listed five patents in the Orange Book covering its donepezil drug product, marketed as ARICEPT®. Ranbaxy was the first to file an ANDA containing a paragraph IV certification seeking FDA approval to market a generic donepezil product, entitling it to 180 days of exclusivity under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Along with its four paragraph IV certifications, Ranbaxy filed a paragraph III certification with respect to one of Eisai's patents (the '841 patent), affirmatively agreeing to stay off the market until

[3] The September 30, 2010 Order makes specific reference to the possibility of reversal by the D.C. Circuit in the *Losartan Appeal*. (*See* D.I. at 1 n.1. ("Sandoz's asserted injury is that if the FDA's current interpretation and application of the delisting rule under 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(CC)) is overruled on appeal, approval of its ANDA could be delayed. (*See* D.I. 17 at 15-16.) This is far too speculative to constitute injury-in-fact....")).

at least the '841 patent expired. Based on these certifications, Eisai did not sue Ranbaxy. Teva also filed two ANDAs for donepezil,[4] and as a second-filer, was required to stay out of the market until Ranbaxy's exclusivity expired unless it could obtain a court decision finding the patents invalid or not infringed, triggering Ranbaxy's exclusivity. Teva, however, challenged all five listed patents, and Eisai sued Teva for infringing the '841 patent. Teva filed declaratory judgment counterclaims, seeking a judgment that its product did not infringe Eisai's four unasserted patents.

Eisai moved to dismiss Teva's counterclaims. The district court granted Eisai's motion, applying *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008), based in part on the fact that the court granted a preliminary injunction that temporarily kept Teva off the market. Under that ruling, even if Teva was able to prove that its product did not infringe Eisai's unasserted patents, it could not market its product until after Ranbaxy's 180-day exclusivity expired – some unknown amount of time after the expiration of the '841 patent. The Federal Circuit disagreed, finding this harm judicially cognizable under Article III, and instead applied its prior precedent, *Caraco Pharm. Labs., Ltd. V. Forest Labs., Inc.*, 537 F.3d 1278 (Fed. Cir. 2008). *See Eisai*, 2010 WL 3895375, at *5-6.

Here, Genzyme convinced this Court to dismiss Sandoz's '083 counterclaim because, *inter alia*, it had both statutorily disclaimed the patent and requested that the FDA delist the patent from the Orange Book. Based on the Federal Circuit's recent decision in *Eisai*, neither action by Genzyme is enough to divest the Court of declaratory judgment jurisdiction. Under *Eisai*, the Federal Circuit has now confirmed that a

[4] Teva's second ANDA was filed by Gate Pharmaceuticals, an unincorporated division of Teva.

statutory disclaimer by the brand company is not sufficient as a matter of law to remove the FDA-approval-blocking injury: "A statutory disclaimer has the effect of cancelling the patent claims, meaning they cannot be reissued or subsequently reinforced. **What matters for our purposes is that all four of the DJ patents remain listed in the Orange Book.**" *Id.* at *3 (emphasis added) (internal citation omitted). Further, Eisai's request that the FDA delist one of its patents (the '760 patent) from the Orange Book had no effect on the Court's conclusion to maintain jurisdiction.[5]

No combination of statutory disclaimers, covenants-not-to-sue, delisting requests or even preliminary injunctive relief obtained by the brand could redress the harm of delaying the second-filer's FDA approval. This is because the injury of "exclusion from the market" was *caused* by Genzyme: "'but-for' the [brand's] decision to list a patent in the Orange Book, FDA approval of the generic drug company's ANDA would not have been independently delayed by that patent." *Id.* at *5. The harm the brand caused to the second-filer in *Eisai* is the same harm Genzyme caused Sandoz in this case. The same result should follow – this Court should hear Sandoz's declaratory judgment counterclaim.

C. Sandoz Cannot Rely on the FDA to Redress the Harm Caused By Genzyme's Listing of the '083 Patent in the Orange Book

The Hatch-Waxman Act includes forfeiture provisions to ensure that second-filers like Sandoz are not improperly kept off the market. *See* 21 U.S.C. § 355(j)(5)(D)(i). Under the failure to market provision, a first-filer forfeits its exclusivity if it fails to market its generic product within specified time periods.

[5] *See* delist request filed by Eisai in the Orange Book for ARICEPT®, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=020690&Product_No=002&table1=OB_Rx.

Id. at § 355(j)(5)(D)(i)(I). Sandoz, as a second-filer, seeks to obtain a "bb date"[6] under this provision, but will be improperly deprived of its forfeiture opportunity under the Court's September 30, 2010 Order. Specifically, no court has yet found the listed patents invalid or not infringed under (bb)(AA), Genzyme has not yet agreed to enter into a settlement agreement with Sandoz under (bb)(BB), and now, under the *Losartan Appeal*, even the date that Genzyme asked the FDA to withdraw the '083 patent from the Orange Book is insufficient to qualify under (bb)(CC). *Id.* at §§ 355(j)(5)(D)(i)(I)(bb)(AA)-(CC).

The *Losartan Appeal* addressed the FDA's application of 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(CC), commonly known as the "delist rule." The FDA previously applied the "delist rule" such that as of the date a brand requested that its patent be withdrawn from the Orange Book, that patent could no longer block FDA approval of any second-filer's ANDA. But the D.C. Circuit reversed in the *Losartan Appeal*, and the FDA can no longer apply the "delist rule" in a way that effectuates a forfeiture of a first-filer's exclusivity. *See Losartan Appeal*, 595 F.3d at 1318 (reversing the FDA's application of the delist rule such that a brand cannot use delisting to deprive the generic of its 180-day exclusivity).

Under the *Losartan Appeal*, the '083 patent still poses a barrier to the FDA's approval of Sandoz's generic version of Hectorol®. Thus, the injury Genzyme caused Sandoz by listing the '083 patent in the Orange Book is not speculative, but real and cognizable. Sandoz can no longer rely on the FDA's

[6] The term "bb date" refers to three qualifying events provided in 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb)(AA)-(CC). The FDA uses, *inter alia*, the "bb date" to calculate when a first-filer forfeits its exclusivity under the failure to market provision.

application of the "delist rule" to ensure its ANDA is not wrongfully blocked by the first-filer for an indefinite period of time based on Genzyme's choice to delist the '083 patent rather than litigate it. On this basis, the Court should grant Sandoz's motion.

III. CONCLUSION

For the forgoing reasons, this Court should grant this Motion for Reconsideration and reinstate Sandoz's declaratory judgment counterclaim for the '083 patent.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 12, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court by CM/ECF, which will send notification of such filing to:

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I further certify that I caused copies of the foregoing document to be served on October 12, 2010, upon the following in the manner indicated:

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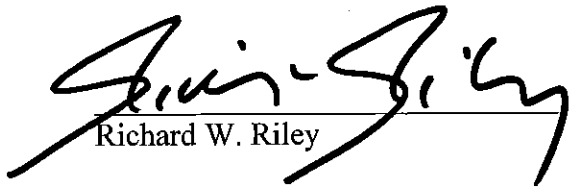

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