IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR PARTIAL RECONSIDERATION OF THE COURT'S SEPTEMBER 30, 2010 ORDER

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiffs Bone Care International LLC and Genzyme Corporation

OF COUNSEL:

Scott K. Reed
Filko Prugo
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

I. INTRODUCTION 1

II. ARGUMENT 1

A. Reconsideration Will Not Result in Amendment of The Order 2

B. There Has Been No Sufficient Change In Controlling Law 6

C. There is No Manifest Injustice to Sandoz 8

III. CONCLUSION 8

TABLE OF AUTHORITIES

Page(s)

CASES

Benitec Austl., Ltd. v. Nucleonics, Inc.,
495 F.3d 1340 (Fed. Cir. 2007) 2

Caraco Pharm. Labs. v. Forest Labs.,
527 F.3d 1278 (Fed. Cir. 2008) ..... Passim

Dentsply Int'l, Inc. v. Kerr Mfg. Co.,
42 F. Supp. 2d 385 (D. Del. 1999) 1

Harsco Corp. v. Zlotnicki,
779 F.2d 906 (3d Cir. 1985) 1

Janssen Pharmaceutica, N.V. v. Apotex, Inc.,
540 F.3d 1353 (Fed. Cir. 2008) 2, 4-5, 8

Max's Seafood Cafe v. Quinteros,
176 F.3d 669 (3d Cir. 1999) 1

Schering Corp. v. Amgen, Inc.,
25 F. Supp. 2d 293 (D. Del. 1998) 1

Teva Pharms. USA, Inc. v. Eisai Co.,
No. 2009-1593, 2010 WL 3895375 (Fed. Cir. Oct. 6, 2010) 2, 6-8

Teva Pharms. USA, Inc. v. Sebelius,
595 F.3d 1303 (D.C. Cir. 2010) 7

RULES AND STATUTES

21 U.S.C. § 355 ..... 5, 7

Local Rule 7.1.5 1

I. INTRODUCTION

Defendant Sandoz Inc. ("Sandoz") has moved for reconsideration of the Court's September 30, 2010 Order granting Plaintiffs Bone Care International LLC and Genzyme Corporation's (collectively "Genzyme's") Motion to Dismiss Sandoz's Declaratory Judgment Counterclaim with respect to U. S. Patent No. 6,903,083 ("the '083 patent") for lack of subject matter jurisdiction. As set forth below, Sandoz has failed to meet the stringent standards applicable, and its Motion for Reconsideration should be denied.

II. ARGUMENT

The decision to grant a motion for reconsideration lies squarely within the discretion of the district court. *See Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 42 F. Supp. 2d 385, 419 (D. Del. 1999). Pursuant to Local Rule 7.1.5, such a motion should be granted only "sparingly." D. Del. LR 7.1.5. "The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985). Specifically, a motion for reconsideration *may* be granted if the moving party shows: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court [issued its order]; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Max's Seafood Cafe v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999). In no instance, however, should reconsideration be granted if it would not result in amendment of an order. *Schering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 295 (D. Del. 1998).

Reconsideration of the Court's September 30, 2010 Order granting Genzyme's Motion to Dismiss Sandoz's Declaratory Judgment Counterclaim with respect to the '083 patent is not proper. *First*, reconsideration will not result in amendment of the Order because Sandoz

cannot show that it will suffer a judicially cognizable injury in fact due to the '083 patent. *Second,* there has been no change in the controlling law sufficient to justify reconsideration because the Federal Circuit in *Teva Pharms. USA, Inc. v. Eisai Co.*, No. 2009-1593, 2010 WL 3895375 (Fed. Cir. Oct. 6, 2010) [hereinafter *Eisai*] simply applied its prior precedent. *Third,* there is no manifest injustice. Sandoz can still accelerate its entry to the market by obtaining a "commercial-marketing trigger" of first-filer Pentech's 180-day exclusivity.

A. Reconsideration Will Not Result in Amendment of The Order

Sandoz's Motion for Reconsideration will not result in amendment of the Order. A declaratory judgment plaintiff bears the burden of proving the existence of an Article III controversy. *See Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1343-45 (Fed. Cir. 2007). A party that does not suffer an injury in fact—that is, an injury that is concrete and actual or imminent, not merely conjectural or hypothetical—lacks that jurisdictional predicate. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.,* 540 F.3d 1353, 1359 (Fed. Cir. 2008).

Sandoz bases its Motion, in part, on the decision of the Federal Circuit in *Eisai.* However, in holding that there was judicially cognizable harm under Article III, the Federal Circuit in *Eisai* simply applied its prior precedent, *Caraco Pharm. Labs. v. Forest Labs.*, 527 F.3d 1278 (Fed. Cir. 2008). As set forth below, the Federal Circuit's decision in *Caraco* is inapplicable to the facts of this case. The possibility that Sandoz will suffer any injury in fact under the circumstances here is purely speculative, and does not create subject matter jurisdiction.

In *Caraco*, second-filer Caraco submitted an ANDA containing Paragraph IV certifications against two patents, the first of which expired eleven years before the second. *Caraco*, 527 F.3d at 1286, 1288. The branded company, Forest, sued Caraco for infringement of

the first patent only; Caraco sought a declaratory judgment that it did not infringe the second. *Id.* at 1288. Forest granted Caraco a covenant not to sue on the second patent and moved to dismiss the declaratory judgment action for lack of subject matter jurisdiction. *Id.* at 1288-89. First-filer Ivax had likewise filed Paragraph IV certifications against both patents. *Id.* at 1286. In a separate suit, Judge Farnan found the first patent valid and infringed, and enjoined Ivax from launching until after the first patent's expiration. *Id.* at 1287. Ivax did not challenge the second patent. *Id.* at 1286.

Because first-filer Ivax could not trigger its own exclusivity period, only two pathways remained open to subsequent ANDA filers who sought to trigger Ivax's exclusivity period before expiration of the first patent:

> ***First***, a subsequent Paragraph IV ANDA filer could obtain a court judgment invalidating [the first patent], which would allow the FDA to approve Ivax's drug. With FDA approval, Ivax would be legally free to sell its generic drug, and its exclusivity period would be triggered on the day of its first commercial marketing. ... (the "commercial-marketing trigger"). ***Second***, a subsequent Paragraph IV ANDA filer could trigger Ivax's exclusivity period immediately—regardless of when Ivax begins marketing its drug—via the court-judgment trigger.

Id. at 1287 (emphasis added)(internal citations omitted). Moreover, if "a subsequent Paragraph IV ANDA filer [was] not able to pursue ***either of these two pathways*** to triggering Ivax's exclusivity period," then Ivax's exclusivity period could not begin until the first patent expired. *Id.* (emphasis added).

Unlike the present case, second-filer Caraco could only trigger Ivax's exclusivity using the court-judgment trigger; the commercial-marketing trigger was not available because Caraco did not assert that the first patent was invalid. *Id.* at 1297 ("Only by obtaining a judgment of noninfringement on both the [first] and [second] patents can Caraco trigger

Ivax's 180-day exclusivity period . . . . Without a judgment of noninfringement on the [second] patent, even if Caraco prevailed against Forest in the separate infringement action on the [first] patent, Caraco would not be able to activate Ivax's exclusivity period via the court-judgment trigger . . . ."))(internal citations omitted). Caraco's inability to pursue ***either of these two pathways*** to trigger Ivax's exclusivity period gave rise to an injury in fact and therefore, a justiciable Article III controversy in that case.

Caraco thus presented a situation in which the validity of the first patent was not in issue, and where the first-filer had lost on infringement but the second-filer potentially could prevail by proving non-infringement. That is not the case here. Here, first-filer Pentech is actively challenging the validity of the first patent, U.S. Patent No. 5,602,116 ("the '116 patent"), which challenge is currently being tried by Judge Dow in the Northern District of Illinois (C.A. No. 10-0112). If Pentech succeeds in invalidating the '116 patent, Pentech's ANDA will be approved and it can launch. Unlike *Caraco*, first-filer Pentech can thereby provide its own "commercial-marketing trigger." Any delay Sandoz may face in receiving final approval thereafter is a consequence of the statutory 30-month stay of Sandoz's ANDA or Pentech's statutory right to 180 days of exclusivity. Such delay is an intended consequence of the Hatch-Waxman Act, and cannot constitute an injury in fact. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361-62 (Fed. Cir. 2008).

Also unlike *Caraco*, here, Sandoz is seeking to trigger Pentech's exclusivity by challenging the validity of the '116 patent. Even if Pentech is unsuccessful in invalidating the '116 patent, should Sandoz obtain a final court decision that the '116 patent is invalid, the FDA

will be able to approve Pentech's ANDA.[1] Pentech could then launch and again provide its own "commercial-marketing trigger." In such circumstances, Sandoz need only wait 180 days for Pentech's exclusivity to expire to obtain final FDA approval and launch. The Federal Circuit in *Janssen* expressly held that a mere delay in FDA approval due to the first-filer exercising its statutory entitlement to exclusivity did not constitute an injury in fact that gives rise to an Article III controversy. *Janssen*, 540 F.3d at 1362.

Therefore, this case is distinguishable from *Caraco*; both Pentech and Sandoz can still accelerate Pentech's 180-day exclusivity via the "commercial-marketing trigger."[2] Sandoz has not been harmed by the dismissal of its declaratory judgment claim on the '083 patent and thus reconsideration will not result in amendment of the Court's September 30, 2010 Order.

Moreover, the second pathway—a "court-judgment trigger"—would only be relevant here if Sandoz could prevail on noninfringement but fail to establish invalidity of the '116 patent.[3] However, Sandoz has not seriously challenged infringement of the '116 patent. Sandoz provided no legal or factual basis for a finding of non-infringement in its notice letter. If Sandoz had any legal or factual basis for such opinion, it should have included it in its notice letter, as required by the Hatch-Waxman Act. 21 U.S.C. § 355(j)(2)(B)(iv)(II). Similarly,

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1 However, as noted in Genzyme's original motion to dismiss Sandoz's counterclaims, there is no reasonable basis from which to assume that this Court will find that the '116 patent is invalid, where the District Court for the Northern District of Illinois has found that the '116 patent is valid. (D.I. 12 at 16.)

2 To the extent that these scenarios also depend upon Pentech's immediate launch upon approval, the Federal Circuit has held that the likelihood that a first-filer will not launch immediately—and will instead delay its launch indefinitely—is too speculative a harm to give rise to an injury in fact. *Janssen*, 540 F.3d at 1362-63; *Caraco,* 527 F.3d at 1296 n.14.

3 As set forth above, a final court decision that the '116 patent is invalid would allow Pentech to launch and would thereby result in the "commercial-marketing trigger."

Sandoz's counterclaim (D.I. 9, ¶¶ 17-19) provides no basis for its boilerplate assertion of non-infringement. Indeed, Pentech stipulated to infringement of the '116 patent. (LDX 14.)[4] Thus the possibility that Sandoz could lose on invalidity but prevail on noninfringement of the '116 patent is highly speculative and renders the "court-judgment trigger" irrelevant here.

B. There Has Been No Sufficient Change In Controlling Law

There has been no change in the controlling law—the recent Federal Circuit decision in *Eisai* is inapplicable to the facts of this case. In *Eisai*, the second-filer, Gate, submitted Paragraph IV certifications against all five Orange Book-listed patents. *Eisai*, 2010 WL 3895375, at *3. The branded company, Eisai, sued Gate for infringement of the first patent; and Gate sought a declaratory judgment of ***noninfringement*** of the four later-expiring listed patents ("the DJ patents"). *Id.* Eisai subsequently disclaimed two of the DJ patents and granted Gate a covenant not to sue on the other two DJ patents. *Id.* Eisai moved to dismiss the declaratory judgment action for lack of subject matter jurisdiction. *Id.* In *Eisai*, Ranbaxy was the first to file Paragraph IV certifications against the DJ patents, and thus was entitled to 180 days of exclusivity. *Id.* at *2. Ranbaxy also filed a Paragraph III certification against the first patent. *Id.* Thus, Ranbaxy could not launch until after the first patent's expiration. *Id.* Eisai did not sue Ranbaxy on the DJ patents.[5] *Id.*

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4 "LDX" refers to the numbered exhibits of the accompanying Declaration Of Christopher E. Loh submitted in support of Genzyme's Motion to Dismiss Sandoz's counterclaims.

5 There were in fact two first-filers in *Eisai*. The other first-filer, Teva, was entitled to 180-days of exclusivity by having submitted the first Paragraph IV certification against the first patent. *Id.* However, this does not change the fact that because Ranbaxy had not triggered its own exclusivity, Gate needed a judgment of non-infringement in respect to all of the DJ patents to obtain a court-judgment trigger of Ranbaxy's 180 day exclusivity period. *Id.* at *4.

As in *Caraco,* FDA approval of Gate's ANDA could not occur until the exclusivity period on the DJ patents had run. *Id.* at *4. But by reason of its Paragraph III certification on the first patent, Ranbaxy could not trigger its own exclusivity via commercial marketing. *Id.* at *2. And because Ranbaxy's exclusivity was based on its Paragraph IV certifications against the DJ patents, Gate could not trigger Ranbaxy's exclusivity without a court judgment of noninfringement in respect of all the DJ patents on which exclusivity was based. *Id.* at *4. This impossibility gave rise to an injury in fact and a justiciable Article III controversy in respect of the DJ patents. *Id.* at *6.

In *Eisai,* there was no way—other than through a declaratory judgment action on the DJ patents—for the second-filer to trigger the first-filer's exclusivity. Again, that is not true in this case. Here, both first-filer Pentech and Sandoz are actively challenging the validity of the '116 patent. If either obtains a final court decision that the '116 patent is invalid, Pentech's ANDA will be approved and Pentech can launch, thereby providing the "commercial-marketing trigger." This is so notwithstanding the decision of the United States Court of Appeals for the D.C. Circuit in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) [hereinafter *Losartan Appeal*] because it is immaterial to the "commercial-marketing trigger" available to Sandoz that the '083 patent remains listed in the Orange Book. Although the Court considered the possibility that the FDA's application of 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (the "delist rule") would be reversed on appeal too speculative to give rise to an injury in fact in the present case, reversal of the delist rule in the *Losartan Appeal* does not require that the Court grant Sandoz's Motion for Reconsideration. As set forth above, Sandoz still cannot show that it will suffer a judicially cognizable harm, and reconsideration will not result in amendment of the Order.

In sum, Sandoz has not been harmed by the dismissal of its declaratory judgment action on the '083 patent. Neither *Eisai* nor the *Losartan Appeal* represent a change in the controlling law that justifies reconsideration here.

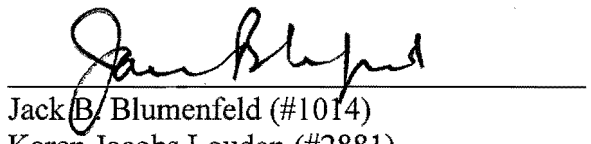
C. There is No Manifest Injustice to Sandoz

Sandoz alleges that "it will be improperly deprived of its forfeiture opportunity under the Court's September 30, 2010 Order." (D.I. 30 at 6.) However, as the Federal Circuit held in *Janssen*, and affirmed in *Eisai*, a second-filer cannot proceed with its declaratory judgment action simply to trigger the first-filer's exclusivity period. *Janssen*, 540 F.3d at 1362-63; *Eisai*, 2010 WL 3895375, at *5-6. In any event, by obtaining a final judgment of invalidity of the '116 patent, Sandoz may still trigger Pentech's commercial launch, and thereby, its 180-day exclusivity period. Thereafter, the only delay in final FDA approval Sandoz may face is an intended consequence of the Hatch-Waxman Act, and cannot constitute an injury in fact. *See Janssen*, 540 F.3d at 1361-62. Accordingly, there is no manifest injustice that justifies reconsideration of the Court's Order.

III. CONCLUSION

Sandoz has failed to meet the stringent standards applicable on its Motion. Sandoz's Motion for Reconsideration of the Court's September 30, 2010 Order should be denied.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiffs Bone Care International LLC and Genzyme Corporation

OF COUNSEL

Scott K. Reed
Filko Prugo
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

October 29, 2010
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CERTIFICATE OF SERVICE

I hereby certify that on October 29, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Richard W. Riley, Esquire
DUANE MORRIS LLP

I further certify that I caused copies of the foregoing document to be served on October 29, 2010, upon the following in the manner indicated:

Richard W. Riley, Esquire — *VIA ELECTRONIC MAIL*
DUANE MORRIS LLP
1100 North Market Street
Suite 1200
Wilmington, DE 19801

Thomas J. Filarski, Esquire — *VIA ELECTRONIC MAIL*
Meredith Martin Addy, Esquire
Stephanie J. Felicetty, Esquire
Abby L. Lemek, Esquire
BRINKS HOFER GILSON & LIONE
NBC Tower – Suite 3600
455 North Cityfront Plaza Drive
Chicago, IL 60611-5599

Jack B. Blumenfeld (#1014)