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 ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS ON PLAINTIFFS' '211, '980 AND '083 PATENTS

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NATURE AND STAGE OF THE PROCEEDING

Defendant Sandoz Inc. ("Sandoz") opposes Plaintiffs Bone Care International LLC and Genzyme Corporation's (collectively, "Genzyme") motion and papers in support thereof pursuant to Fed. R. Civ. P. 12(b)(1) (*see* D.I. 11, 12 & 13) for an order dismissing Sandoz's Counterclaims Counts III-VII (D.I. 9, ¶ 20-56) because a real and justiciable Article III controversy exists over U.S. Patent Nos. 7,148,211 ("'211 patent"), 5,707,980 ("'980 patent") and 6,903,083 ("'083 patent").

Sandoz asserts these declaratory judgment counterclaims to prevent Genzyme from attempting to limit competition in the marketplace for the generic drug doxercalciferol by manipulating the Hatch-Waxman Act.[1] By purposely listing patents in the FDA's Orange Book, and then later refusing to litigate those patents against Sandoz, a potential generic competitor, Genzyme is causing real and immediate harm. Sandoz attempted to negotiate a consent decree or settlement order with Genzyme that would have resolved all harm, but Genzyme refused and sought relief through this motion. However, the express provisions of the Hatch-Waxman Act and the policies for its enactment support Sandoz's declaratory judgment counterclaims and require denial of Genzyme's motion to dismiss.

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)) ("Hatch-Waxman Act"), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

SUMMARY OF ARGUMENT

1. Genzyme is harming Sandoz by using the '211 patent to exclude Sandoz from the marketplace for doxercalciferol. By listing its patents in the Orange Book, then refusing to litigate the merits of the '211 patent, Federal Circuit precedent holds that declaratory judgment jurisdiction has been established. Genzyme's unilateral covenant not to sue does not remove the harm to Sandoz as a matter of law under *Caraco* and other district court decisions.

2. Sandoz's harm is real and immediate under *MedImmune*. Sandoz suffers injury-in-fact because its ability to secure timely final approval of its ANDA is being prevented by Genzyme. Regardless of the outcome of the first-filer's litigation, Sandoz risks being held from the market longer than the first-filer's 180-day exclusivity period.

3. Genzyme has further caused real harm to Sandoz by listing the '980 and '083 patents in the Orange Book. Genzyme's attempt to delist these patents does not remove the harm. Under the current application of the statute, the FDA will not grant final approval to Sandoz until it first determines exclusivity rights related to the patents listed in the Orange Book. The FDA's application of the Hatch-Waxman statute in view of a delisting request is being challenged in court, and until finally resolved, the harm caused by uncertainty remains.

4. This court should exercise its discretion to hear Sandoz's '211, '980 and '083 counterclaims because doing so will serve the policies behind the Hatch-Waxman Act of promoting pioneer research and development of new drugs while encouraging manufacturers to bring cost-effective generic drugs to market through a complex incentive structure. As this case proceeds through discovery, and turns toward claim construction and trial, the harm caused by Genzyme will increase as the time Sandoz will have to defend itself against these patents shortens.

COUNTERSTATEMENT OF FACTS

Orange Book Listing

When Genzyme filed its New Drug Application ("NDA") with the FDA seeking approval for its drug product Hectorol®, it listed four patents in the Orange Book: the '211, '980, and '083 patents, and U.S. Patent No. 5,602,116 ("'116 patent"). *See* § 355(b)(1). The '211 patent expires on September 14, 2023. Genzyme first listed the '980 patent's expiration date as August 17, 2010, though Genzyme now concedes this date is wrong and that the '980 patent in fact expired August 2, 2008. (Pls' Br. at 7.) The incorrect Orange Book listing for the '980 patent, however, remains.

Despite Genzyme's offer of a covenant not to sue for the '211 patent, its requests to delist the '980 and '083 patents, and its disclaimer of the '083 patent, all four patents remain listed in the Orange Book for Hectorol® as follows:

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
021027	001	5602116	Feb 11, 2014			U-321	
021027	001	5707980	Aug 17, 2010			U-321	Y
021027	001	6903083	Jul 18, 2021	Y	Y		Y
021027	001	7148211	Sep 14, 2023		Y		

As long as the '211, '980 and '083 patents remain in the Orange Book, Sandoz risks untimely FDA final approval of its ANDA if they are not challenged.

FDA Policy

FDA practice is to keep these three patents in the Orange Book because a paragraph IV certification was filed on them. To the extent any 180-day exclusivity is based upon the '211 patent, the FDA will make exclusivity determinations on or around the last day prior to a party receiving final approval. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B). Similarly, despite the delisting requests of the '980 and '083 patents, the FDA may not remove the '980 and '083 patents from the Orange Book, despite Genzyme's delisting requests. *Id.* The FDA follows this practice so it can determine 180-day exclusivity, if at all, at the time of final ANDA approval. *Id.*; *see also Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 9-11 (D.D.C. 2008).

The FDA's policy has been challenged in court. *See Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009). Teva unsuccessfully argued that the FDA's application of the "delisting rule" to serve as a basis to forfeit 180-day exclusivity is arbitrary and capricious. *Id.* at 55-58. This case is currently on appeal to the Court of Appeals for the District of Columbia. *See id., appeal docketed*, No. 09-5308 (D.C. Cir. Aug. 25, 2009) (awaiting oral argument).

Sandoz's Notice To Genzyme

Sandoz filed ANDA No. 91-333 with the FDA for approval of its doxercalciferol drug product, and notified Genzyme pursuant to § 355(j)(2)(B). Sandoz attached an Offer for Confidential Access and a Detailed Statement of the legal bases for its paragraph IV certifications concerning all four of Genzyme's Orange Book-listed patents covering Hectorol®. *See* §§ 355(j)(2)(B)(iv) and (j)(5)(C)(i)(III). Genzyme filed suit within the 45-day period contemplated by the statute, but only alleged infringement of the '116 patent. When Genzyme failed to bring suit against Sandoz for infringement of the other three patents listed in the Orange

Book, the Hatch-Waxman statute authorized Sandoz to file a declaratory civil action to obtain patent certainty under §§ 355(j)(5)(C)(i) and 271(e)(5).

Genzyme's Related Pentech Litigation

In Genzyme's suit against Pentech Pharmaceuticals, Inc. and Cobrek Pharmaceuticals, Inc. (collectively, "Pentech"), No. 08-cv-1083 (N.D. Ill.) (RMD) (MCA), Pentech filed paragraph IV certifications with the FDA against the '116, '980 and '083 patents, and notified Genzyme of the same. Genzyme asserted, but later withdrew its claim on the '083 patent, and pursued a claim on the '116 patent. No action was taken by either party on the '980 patent.

A year later, Pentech filed a paragraph IV certification with the FDA regarding the '211 patent, and gave notice. Genzyme refused to sue Pentech for infringing the '211 patent, and Pentech failed to file a declaratory judgment counterclaim against Genzyme. It was not until August 2009, after Genzyme had statutorily disclaimed the '083 patent to the PTO, granted Pentech a covenant not to sue ("CNS") on the '083 patent, and obtained a consent judgment, that Pentech even addressed the '211 patent.

Just as Genzyme has tried here, it sought to insulate the '211 patent from litigation by offering a CNS to Pentech. (*See* Ex. 1, *Pentech* Dkt. No. 204, Loh Ex. D, Email negotiations between Genzyme's and Pentech's counsel.) Genzyme opposes Pentech's attempt to seek a final determination of liability under the '211 patent. (*See* Ex. 2, *Pentech* Dkt. No. 203 at 3-5, Pls' Supp. Memo. re Aug. 14, 2009 Order.) The Illinois district court is still considering whether to grant Pentech leave to add a declaratory judgment counterclaim at such a late stage of that case. (*See* Ex. 3, *Pentech* Dkt. No. 196 at 6-7, Minute Entry, requesting additional briefing on the status of the '211 patent.)

Genzyme and Pentech stipulated to infringement of claim 7 of the '116 patent on March 24, 2009. (D.I. 13, Ex. 14.) Genzyme will drop all other claims against Pentech if they invalidate claim 7 at trial. (*Id.*) The parties thus have streamlined the case and it likely will reach final resolution sooner than it would have had infringement remained in the case; however, as the date of this brief, no trial date appears on the docket. Finally, in the Illinois action, Genzyme agreed with Pentech to delay any potential "at risk" launch by Pentech at least seven days beyond the expiration of the 30-month stay. (*See* Exs. 4 & 5, *Pentech* Dkt. Nos. 201, 230.)

ARGUMENT

1. Jurisdiction Was Established By Genzyme's Listing The '211 Patent In The Orange Book And Refusing To Assert It Against Sandoz

Genzyme is unlawfully creating a bottleneck of second-filers who cannot enter the market, even if all of Genzyme's patents are invalid or not infringed, based upon Genzyme's selective assertion of less than all of its Orange Book-listed patents. Relying upon a skewed view of the "intended result of the Hatch-Waxman Act," (Pls. Br. at 11), Genzyme wrongly seeks to protect its market for Hectorol® as that drug heads for generic competition. The undisputed fact remains that Genzyme listed four patents in the Orange Book covering the drug, and since that time, has refused to adjudicate the merits of all its listed patents in a single forum, or enter into a consent decree or settlement order where appropriate. Genzyme is doing the same thing here, and its conduct establishes declaratory judgment jurisdiction. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1343 (Fed. Cir. 2007) ("*Teva*") (declaratory judgment jurisdiction where a patentee lists patents in the Orange Book but will not litigate them).

The *Teva* court, in first recognizing declaratory judgment jurisdiction in this context, criticized the patentee for selectively enforcing its patents:

> By filing a lawsuit on only one of its five patents certified under paragraph IV in Teva's ANDA, [the patentee] has tried to simultaneously leverage the benefits provided to a patentee under the Hatch-Waxman Act and avoid the patentee's accompanying responsibility. [The patentee's] suit against Teva has invoked the statutory automatic 30-month stay and is concurrently insulating the four method patents from a validity challenge…. [The patentee's] action insulates it from any judicial determination of the metes and bounds of the scope of the claims of its four Famvir® method patents in relation to design-around, a determination that is central to the proper function of our patent system and is a central purpose of the Hatch-Waxman Act.

Id. The Court should reject Genzyme's "gaming" of the system; it is not for Genzyme to upset this carefully-constructed balance that Congress designed to incentivize the research and development of new drugs, while also encouraging the production of low cost generic drugs for the public well-being. *Id.* at 1342 & n.7 (citing 149 Cong. Rec. S15882-03, S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of the Senate HELP committee)).

The Federal Circuit stated in *Teva* – and this Court followed – what "***establishes*** a justiciable declaratory judgment controversy in the Hatch-Waxman context": (1) the patentee lists patents in the Orange Book; (2) the ANDA applicant files paragraph IV certifications against them; and (3) the patentee brings an action against the submitted ANDA on one or more of the patents. *Merck & Co., Inc. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 423 (D. Del. 2007) (Sleet, J.), *affirmed-in-part, vacated-in-part as moot*, 287 Fed. App'x 884, 888-89 (Fed. Cir. 2008) (citing *Teva*, 482 F.3d at 1344). As the Federal Circuit noted, "[t]he combination of these three circumstances is **dispositive** in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or some of the paragraph IV certified patents." *Id.* (emphasis added).

A. Under *Caraco*, A Unilateral Covenant Not To Sue Does Not Divest The Court Of Its Established Declaratory Judgment Jurisdiction[2]

Genzyme's offer of a CNS on the '211 patent does not divest this Court of jurisdiction. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1297 (Fed. Cir. 2008) *cert. denied*, 129 S. Ct. 1316 (2009). The *Caraco* court held "there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" even in the presence of a CNS. *Id.* at 1290, 1296-97 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 771 (2007)) (citation omitted)). In other words, *Caraco* stands for the maxim that a CNS does not remove declaratory judgment jurisdiction when a party lists patents in the Orange Book and then later refuses to enforce them. Declaratory judgment jurisdiction exists here because Genzyme listed its four patents in the Orange Book, sued Sandoz for infringing the '116 patent, but insulated its '211 patent for another day. *Caraco*, 527 F.3d at 1289; *see also Teva*, 482 F.3d at 1343.

In *Caraco*, Forest successfully sued the first-filer, Ivax, on only one of two Orange Book-listed patents, resulting in a judgment of patent validity and infringement. *Id.* at 1286. Caraco, as the second-filer, filed paragraph IV certifications for both listed patents but Forest only filed suit on the same patent it had successfully asserted against Ivax. *Id.* at 1288. In response to a declaratory judgment counterclaim against the unasserted patent, Forest unilaterally granted Caraco a CNS and successfully moved to dismiss the counterclaims under Rule 12(b)(1). *Id.* at 1288-89. The Federal Circuit reversed, however, holding that a controversy existed – even in view of a CNS – because only a judgment on the merits or a consent decree regarding the

[2] Sandoz recognizes its burden to prove jurisdiction exists here, by showing (1) it has standing – including having an injury-in-fact that is both traceable to Genzyme and redressible by a favorable judgment, (2) the case is ripe, and (3) not rendered moot at any stage. *Caraco*, 527 F.3d at 1291-97. Genzyme's brief concedes all but standing, and only then complains of Sandoz's lack of an injury-in-fact, so Sandoz responds in kind.

unasserted patent would remove the FDA approval-blocking injury Forest caused to Caraco. *Id.* at 1293 n.11, 1297.

The *Caraco* decision thus encourages patentees to litigate the merits of all of their listed patents at once to increase patent certainty and to comport with the policies driving the MMA. *Id.* at 1285-86. *Caraco* also teaches that when patentees try to play games by suing similarly-situated defendants on different listed patents, or by using a CNS instead of the statutorily-recognized settlement order or consent decree in resolving disputes, jurisdiction will exist for defendants to join all the patents at once. *Id.* at 1285-86, 1293 n.11, 1297. Because Genzyme is improperly using a CNS to wrongfully deprive Sandoz of its right to a judicial determination regarding the patents blocking Sandoz from timely marketing its product, jurisdiction exists here under *Caraco*.

Genzyme, however, focuses on whether Sandoz's injury stems from a reasonable apprehension of being sued by Genzyme for infringement, but that is the wrong focus, factually and legally. (Pls' Br. at 1.A.) Genzyme harms Sandoz, as a second-filer, by insulating its listed patents to protect its drug market by limiting competition to one generic competitor for 180 days. Sandoz must litigate any 180-day exclusivity based on the '211 patent to cause a forfeiture. If Sandoz is deprived of this litigation, it risks an incorrect and untimely final approval from the FDA. This is precisely the injury the Federal Circuit sought to redress in *Caraco*. 527 F.3d at 1297.[3]

[3] Although *Caraco* was decided under pre-MMA (2000) law, and this Court must apply post-MMA law (2003), the Federal Circuit determined the basis for its decision applied to both pre- and post-MMA scenarios. *Id.* at 1285 n.4. Under the pre-MMA (2000) version of the statute, there were only two ways 180-day exclusivity was "triggered," including (1) the first-filer taking its product to market, or (2) a judgment of invalidity or non-infringement of all the patents covering the product. *See Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 357 (D. Del. 2009) (Farnan, J.) (citing *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 189-90 (S.D.N.Y. 2000). When a patentee refused to litigate against the second-filer, the second-filer was left without recourse. The MMA (2003) attempted to curb exclusivity "parking" by adding a number of ways a second-filer could enter the market under the "failure to market" forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I). "Thus, under both the pre-2003 and current

Genzyme also pays lip-service to controlling legal standards for jurisdiction in its brief, but then applies the wrong law. For example, Genzyme cites *MedImmune* for the proper "all the circumstances" test to determine whether Article III jurisdiction exists, but then applies the overruled "reasonable apprehension of suit" test. (Pls' Br. at 1.A.) When properly interpreted and applied, *MedImmune*'s "all the circumstances" test was intended to broaden the court's declaratory judgment jurisprudence to the extent permissible under Article III. *Teva*, 482 F.3d at 1338. Similarly, Genzyme misdirects this Court to inapposite[4] non-Hatch-Waxman opinions by the Federal Circuit and other district courts in an effort to avoid unfavorable, but binding precedent, namely *Caraco* and *Teva*.

B. *Janssen* Does Not Change The Outcome Because Sandoz Has Never Stipulated To The Validity Or Infringement Of Genzyme's Listed Patents

Genzyme wrongly urges this Court to follow *Janssen v. Apotex*, 540 F.3d 1353 (Fed. Cir. 2008). (Pls' Br. at 12-13.) In *Janssen*, the first-filer, Mylan, lost its challenge in the district court against the '663 patent. *Id.* at 1357-58. The second-filer, Teva filed a paragraph III certification against the '663 patent. *Id.* at 1358. Apotex, the third-filer, filed a paragraph IV certification against the '663 patent and Janssen sued Apotex only on that patent. *Id.* Apotex filed declaratory judgment counterclaims as to all the other Orange Book-listed, but unasserted patents. Janssen then countered by executing a unilateral CNS and successfully moved to dismiss the Apotex counterclaims in the district court.

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versions of Hatch-Waxman, a [second-filer] can hasten its entry into the market by establishing the invalidity or non-infringement of the NDA holder's Orange Book patents." *Dey*, 595 F. Supp. 2d at 357 (footnote omitted).

[4] Genzyme cites, for example, *Benentec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007) and *Ours Data Tech., Inc. v. Data Drive Thru, Inc.*, No. C 09-00585, 2009 U.S. Dist. LEXIS 64779 at *8-9 (N.D. Cal. July 27, 2009) in its discussion of what is required to support declaratory judgment jurisdiction. (Pls' Br. at 10 & n. 4.) However, the Federal Circuit has clarified that declaratory judgment counterclaims are "***highly different in the highly-regulated pharmaceutical context***, in which a manufacturer is not permitted to market a drug without FDA approval." *See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 n.7 (Fed. Cir. 2008) (emphasis added).

Less than a year later, Apotex stipulated that it would be bound by the Federal Circuit's decision on appeal with respect to the '663 patent. *Id.* The Federal Circuit found the '663 patent valid and infringed in the Mylan case, and Apotex was similarly bound by its stipulation. *Id.*

Apotex argued on appeal that the Federal Circuit's decision in *Caraco* was directly on point, but the Federal Circuit distinguished *Caraco* based on the stipulation:

> We agree with the parties that **if [the third-filer] had not stipulated to the validity of the [previously litigated] patent, then *Caraco* would have been controlling.** However, [the third-filer] stipulated to the validity, infringement, and enforceability of [that] patent…. Therefore, while the harm that created a justiciable Article III controversy in *Caraco* was present when [the third-filer] filed its counterclaims…. that harm ceased to exist upon [the third-filer's] stipulation.

540 F.3d at 1360 (emphasis added). As the court made clear, declaratory judgment jurisdiction exists against a patent listed in the Orange Book but not asserted by the patentee until the generic manufacturer does something to destroy it. *See id.* Here, Sandoz has done nothing to destroy jurisdiction. It certainly has not stipulated to be bound by any other decision on these patents as did Apotex. Rather, Sandoz vigorously disputes Genzyme's allegations of infringement, and Sandoz challenges liability under Genzyme's listed patents. *Janssen*, accordingly, does not apply.

2. This Court Should Not Entertain Genzyme's Allegations That Sandoz's Injury Is Merely Speculative

The Court need not venture into speculation, as Genzyme argues it will; Sandoz's harm is real and immediate today. Sandoz is harmed because its ability to secure approval of its ANDA has been prevented by Genzyme. Sandoz, moreover, is being deprived of its opportunity to seek a final determination by the Court of the merits of all the patents Genzyme listed in the Orange Book. *See Caraco*, 527 F.3d at 1291. This harm only increases as this litigation progresses over

time. The parties are set to begin discovery, and Sandoz needs just as much time to make its case against the '211 patent as it does for the other patents.

Genzyme argues that *Caraco* doesn't apply – *yet* – because there has been no decision with respect to the '116 patent. (Pls' Br. at 17-18.) But this argument only delays the inevitable. Resolution of the '116 patent will occur, and Sandoz will be harmed by an unsuccessful patent challenge or settlement by the first-filer. Genzyme's chart of "possible outcomes," moreover, simply does not apply because it was crafted "absent any counterclaim against the '211 patent[.]" But Sandoz *did* file a counterclaim against the '211 patent. In doing so, Sandoz did not place itself on the same footing as any first-filer in this case, unlike Apotex did in *Janssen*. *See Janssen*, 540 F.3d at 1361. If the Court considers this chart at all, it must also consider what outcomes Genzyme left out – all of which cause precisely the harm Sandoz complains of here – the first-filer could lose, settle, or delay its launch.

1. *Genzyme Defeats The First-Filer*

If the first-filer loses its validity challenge against the '116 patent, then Sandoz will be in the exact position as the *Caraco* second-filer. Should that happen, Genzyme will have successfully insulated itself from a judicial determination as to all the patents it listed in the Orange Book. Sandoz, and all other generic manufacturers, would be stuck in a bottleneck until February 11, 2014.[5]

2. *Genzyme Settles With The First-Filer*

Sandoz is similarly stuck in a bottleneck should Genzyme settle with any first-filer in this case. Several district courts have denied a brand's motion to dismiss a second-filer's declaratory judgment counterclaims, despite the brand's offer for a CNS, where the brand manufacturer

[5] February 11, 2014 is the expiration date of the '116 patent.

orchestrated a settlement with the first-filer. *See, e.g.*, *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009) (Farnan, J.) (denying motion to dismiss based on FDA approval-blocking injury due to settlement agreement between brand and the first-filer), *certification denied*, 2009 WL 1043892, at *2 (D. Del. Apr. 16, 2009); *Dr. Reddy's Labs., Ltd. v. Astrazeneca AB*, No. 08-2496 (JAP), 2009 WL 3241699, at *1-2 (D.N.J. Feb. 23, 2009) (reinstating previously-dismissed counterclaims based on *Caraco* due to settlement between brand and first-filer); *Ivax Pharms., Inc. v. AstraZeneca AB*, No. 08-2165 (JAP), 2009 WL 3208656, at *1-2 (D.N.J. Feb. 20, 2009) (reinstating previously-dismissed counterclaims based on *Caraco* and due to settlement between brand and first-filer).[6] This is because a settlement causes the very same injury as in *Caraco*: any second-filer who cannot challenge all the patents in court must wait until the launch date the parties to the settlement have chosen. *See Dey*, 595 F. Supp. 2d at 362 (applying *Caraco*, not *Janssen*, based on the "policy objectives of the Hatch-Waxman Act" and to "encourage the early resolution of patent disputes when subsequent Paragraph IV ANDA filers are blocked…") (internal quotation marks omitted).

There is nothing stopping Genzyme from settling with any first-filer in this case and immediately blocking the entire generic market if Genzyme's present motion to dismiss is granted. This Court's decision in *Dey* is instructive: Breath was entitled to 180-day exclusivity as the first filer of paragraph IV certifications as to all six Orange Book-listed patents. *Id.* at 358. The second-filer, Dey, certified the same patents as either invalid or not infringed, but Sepracor only sued them on 5 out of the 6 patents, offering a CNS for the unasserted patent. *Id.* Sepracor then entered into an out-of-court settlement agreement with Breath, preventing it from going to

[6] In both *Dr. Reddy's* and *Ivax*, the district court granted Astrazeneca's motions to dismiss based on its admittedly incorrect application of Federal Circuit precedent. The court granted the defendants' motion to reconsider, and reinstated the declaratory judgment counterclaims. (*See* Ex. 6, Hr'g Tr. Jan. 12, 2009.)

market until August, 2012. *Id.* Shortly thereafter, Sepracor moved to dismiss Dey's declaratory judgment counterclaim. *Id.* This Court denied Sepracor's motion because "the sole effect [of Dey prevailing on its declaratory judgment counterclaim] would not be to simply destroy Breath's exclusivity period. Rather, Dey could also potentially go to market well in advance of August 2012…." *Id.* at 362. Just as in *Dey*, Sandoz, by challenging all of the listed patents, could both get to market early and cause a forfeiture of exclusivity of any first-filer who has settled. An Article III controversy exists.

3. *The First-Filer Defeats Genzyme*

If the first-filer wins its validity challenge against the '116 patent, the FDA can grant final approval of its ANDA and it can go to market. Should the first-filer delay its launch of its product, Sandoz could not cause a forfeiture of 180-day exclusivity in the absence of the '211 counterclaims.

* * * * * *

All Genzyme's "speculative" argument does is set up a catch-22 in its favor. Genzyme first successfully dismisses Sandoz's '211 counterclaims now because it calls the harm speculative. Then, just as it did when Pentech sought leave to add a declaratory judgment counterclaim against the '211 patent in the Illinois suit, Genzyme will oppose a future attempt by Sandoz to add the '211 patent in the case, claiming it will be prejudicial to add that patent at such a late stage of the proceeding. This scenario is not speculative. Rather, in a memorandum to the court in *Pentech*, Genzyme argued against adding the '211 declaratory judgment counterclaim, stating:

> "[f]orcing the parties to litigate the '211 patent alongside the '083 and '116 patents will not save the parties or the Court time or money; instead, it will require substantial amounts of new discovery, including the production of new documents, the depositions of new witnesses and the retention of new experts… as the Court knows and as the parties agree, it is important that a trial take place

> well before July 2010, when the automatic stay on the FDA's approval of Pentech's generic drug expires. **Any belated attempt now to add declaratory judgment claims against an entirely new patent will jeopardize a pre-July 2010 trial date**."

(Ex. 2 at 4-5 (emphasis added).)

Sandoz's harm is real today, as the outcomes are known today. Sandoz's harm only grows worse as time passes. Discovery opportunity will be lost, and claim construction and other orders will issue as the pre-trial schedule lapses and trial takes place. Sandoz should not be put to this harm and prevented from challenging now the patents that Genzyme listed in the Orange Book.

3. A Real Controversy Still Exists For The '980 and '083 Patents, And Dismissing Sandoz's Counterclaims At This Time Would Be Prejudicial

While Genzyme correctly states that it requested delisting of its patents from the Orange Book (*see* D.I. 12 at 18), the FDA's application of the "delist rule" under 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(CC)) is currently being challenged in court. *See Teva Pharms., USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009).

Teva was the first generic manufacturer to file a paragraph IV certification on Orange Book-listed patents covering Merck's pioneer drugs Cozaar and Hyzaar. *Id.* at 47-48. When Teva notified Merck of its paragraph IV certification against the '075 patent, instead of filing suit, Merck requested that the FDA delist the '075 patent from the Orange Book. *Id.* at 48. Teva's ANDA also contained paragraph III certifications as to Merck's two other Orange Book-listed patents, the '069 and '197 patents, and the FDA could not approve Teva's ANDA until Merck's patents and pediatric exclusivities expired. *Id.* Under the FDA's application of the Hatch-Waxman Act's failure to market forfeiture provision in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), and based on Merck's request to delist the '075 patent from the Orange Book, the FDA concluded that Teva forfeited its 180-day exclusivity with respect to both

drugs. *Id.* Teva filed for a preliminary injunction to enjoin the FDA's application of the "delisting rule" to cause Teva to forfeit its exclusivity as contrary to the Administrative Procedures Act. *Id.* at 48-49; *see also* 5 U.S.C. § 706(2)(A).

The district court upheld the FDA's actions, however, as not "arbitrary, capricious, an abuse of its discretion, or otherwise not in accordance with the law." *Id.* at 55, 55-58 (quoting §706(2)(A)). Teva's appeal is pending. *See id., appeal docketed,* No. 09-5308 (D.C. Cir. Aug. 25, 2009) (awaiting oral argument). Sandoz should not be forced to gamble on whether the D.C. Circuit will affirm the district court's opinion, currently on appeal, to protect its legal interests in this action.

Genzyme's actions speak louder than its words. If it truly believed that the parties do not have "adverse legal interests" with respect to the '980 and '083 patents based on Genzyme's delisting of the patents from the Orange Book, it would have no problem signing a consent decree or settlement order stating Sandoz's product does not infringe. (D.I. 12 at 18-19.) In fact, Genzyme gave Pentech that very same relief on the '083 patent (*see* Pls' Br. at 8), but Genzyme refuses to do so here. The Federal Circuit called a consent decree "the best approach" to "avoid costly litigation" and "resolve the controversy between the parties." *Caraco,* 527 F.3d at 1293 n.11. Genzyme's unreasonable refusal with respect to the '980 and '083 patents further supports Sandoz's position that there is a definite and concrete controversy here.

4. This Court Should Exercise Its Discretion To Hear Sandoz's Declaratory Judgment Counterclaims Because Doing So Serves Policies Driving The Hatch-Waxman Act

This Court should exercise its discretion to hear Sandoz's declaratory judgment counterclaims because Genzyme's calculating conduct should not be rewarded with decreased generic competition. *See Merck,* 488 F. Supp. 2d at 422, *affirmed-in-part, vacated-in-part as moot,* 287 F. App'x at 888-89 (Fed. Cir. 2008) (any injury from delay was rendered moot

because the FDA dissolved Apotex's 30-month stay and Teva began marketing its drug) (quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 819 (Fed. Cir. 1996)). The statute itself incentivizes generic manufacturers to quickly bring generic drugs to market using 180-day exclusivity. To that end, second-filers are aware they sometimes must wait to enter the market. However, the Hatch-Waxman Act did not intend the *added harm and delay* when a brand manufacturer takes active steps to insulate its patents from litigation. Genzyme's collective action – including its insulation of CNSs relating to the '211 patent from final determination, and by its unreasonable refusal in view of FDA policy to grant Sandoz a consent decree or settlement order to resolve the controversy regarding the '980 and '083 patents – amounts to this *added harm and delay* that this Court must address.

This Court previously declined to hear a second-filer's declaratory judgment counterclaims regarding unasserted patents in view of a CNS prior to the Federal Circuit's decisions in *Caraco* and *Janssen*. *See Merck*, 488 F. Supp. 2d at 424. This Court's discussion of "Manipulation of Court Jurisdiction" is right on. *See id.* at 424-26.

> Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme…. This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. **In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible**.

Id. at 424 (emphasis added).

Since 2007, the Federal Circuit and other district courts have addressed this very issue in favor of the generic declaratory judgment plaintiff. *See, e.g.*, *Caraco*, 527 F.3d at 1297, *Dey*, 595 F. Supp. 2d at 362, *Dr. Reddy's*, 2009 WL 3241699, at *1-2, *Ivax*, 2009 WL 3208656, at *1-2. Under the more liberal, "all the circumstances" *MedImmune* test, courts are refusing to

cause the practical, harmful result of dismissing declaratory judgment counterclaims against patents listed in the Orange Book but not asserting in the face of a paragraph IV certification. *Id.* While the facts of these cases will always differ slightly from here, under all the circumstances, Genzyme's actions, like those of previous patent holders, are causing immediate harm.

CONCLUSION

For the foregoing reasons, Sandoz has established that a justiciable controversy exists over the '211, '980 and '083 patents. Accordingly, Genzyme's motion to dismiss should be denied.

Respectfully submitted,

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