IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ORDER

WHEREAS, on November 12, 2009, the plaintiffs filed a motion to dismiss Sandoz's counterclaims (D.I. 11) on US Patent Nos. 7,148,211 (the "'211 Patent"), 5,707,980 (the "'980 Patent"), and 6,903,083 (the "'083 Patent");

WHEREAS, the court concludes that Sandoz has not established injury-in-fact with respect their declaratory judgment claims against the '083 and '980 patents;[1]

WHEREAS, the court concludes that Sandoz has established all the requirements for standing and subject matter jurisdiction with respect to their declaratory judgment claims against the '211 Patent, and that the plaintiffs' offer to give them a covenant not to sue ("CNS") is not sufficient to eliminate the controversy between the parties;[2]

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[1] The parties do not dispute that the '980 Patent expired on August 2, 2008. (*See* D.I. 13, Ex. 4). Indeed, that patent has now expired even under the incorrect expiration date of August 17, 2010 originally listed in the Orange Book. (*See id.* at Ex. 3, D.I. 17 at 3). Thus, the court concludes that there is no longer any risk that approval of Sandoz's ANDA could be delayed due to the '980 Patent. With respect to the '083 Patent, the plaintiffs have disclaimed this patent and dedicated it to the public. (*See* D.I. 13, Ex. 1.) They also have requested that the FDA delist it from the Orange Book. (*Id.* at Ex. 2.) 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, and the possibility that Sandoz's ANDA approval could be delayed on this basis is rendered even more remote by the plaintiffs' dedication of the patent to the public. While it is true that the plaintiffs could have entered into a consent decree with respect to these patents, the highly speculative nature of Sandoz's alleged injuries-in-fact renders their claims non-justiciable even in the absence of such a decree.

[2] In contrast to their actions with respect to the '083 and '980 patents, the plaintiffs do not claim that they have taken any actions to delist the '211 Patent from the Orange Book or otherwise ensure that approval of Sandoz's

WHEREAS the court has considered the parties' arguments, written submissions, and the applicable case law;

IT IS HEREBY ORDERED that the plaintiffs' motion to dismiss (D.I. 11) is GRANTED IN PART AND DENIED IN PART.[3]

Dated: September 30, 2010

CHIEF, UNITED STATES DISTRICT JUDGE

ANDA will not be delayed on account of the '211 Patent. Rather, the plaintiffs' sole basis for dismissal of the '211 Patent counterclaim is that they have offered Sandoz a CNS, which they assert "eliminate[s] any apprehension of suit" with respect to that patent. As the Federal Circuit held in *Caraco Pharm. Labs. v. Forest Labs*, however, offering a covenant not to sue does not remove declaratory judgment jurisdiction when a party lists patents in the Orange Book and then later refuses to enforce them, since non-first filers still face delayed approval of their ANDAs even with a CNS. 527 F.3d 1278, 1290-97 (Fed. Cir. 2008). This case does not fall into the exception carved out by the Federal Circuit in *Janssen*, because the parties have not stipulated to the validity of a previously litigated patent-in-suit, a condition which the court stated was the "key difference between *Caraco* and this case." *See Janssen Pharmaceutica v. Apotex, Inc.*, 540 F.3d 1353, 1360-61 (Fed. Cir. 2008).

If the plaintiffs truly wished to eliminate the controversy with Sandoz over the '211 Patent, it could have agreed to Sandoz's offer to enter into a consent decree or settlement order with respect to that Patent. (*See* D.I. 13, Ex. 13.) The plaintiffs' decision not to do so and instead to offer only a covenant not to sue renders Sandoz's counterclaim on the '211 Patent justiciable.

[3] Specifically, the court grants the motion and dismisses the counterclaims pertaining to the '083 and '980 patents. *See* footnote 1. The court denies, however, the motion with respect to the '211 Patent. *See* footnote 2.