

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SHOULDER INNOVATIONS, LLC,

Plaintiff,

v.

ASCENSION ORTHOPEDICS, INC.,

Defendant.

HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NO. 11-810
(JEI/AMD)

OPINION

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
By: Jack B. Blumenfeld
Julia Heaney
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
Counsel for Plaintiff

KNOBBE, MARTENS, OLSON & BEAR, LLP
By: Joseph F. Jennings
Joseph S. Cianfrani
2040 Main Street
Irvine, CA 92614
Counsel for Plaintiff

KNOBBE, MARTENS, OLSON & BEAR, LLP
By: Brian C. Horne
10100 Santa Monica Boulevard
Suite 1600
Los Angeles, CA 90067
Counsel for Plaintiff

BAYARD, P.A.
By: Richard D. Kirk
Stephen B. Brauerman
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
Counsel for Defendant

RITCH, EVEN, TABIN & FLANNERY
By: Mark W. Hetzler
Christine A. Pompa
120 South LaSalle Street, Suite 1600

Chicago, IL 60603
Counsel for Defendant

IRENAS, Senior District Judge¹:

This patent infringement suit appears before the Court on Plaintiff's motion to dismiss pursuant to Fed. R. Civ. P. 41(a)(2) (Dkt. No. 20). The motion is denied for the reasons stated below.

I.²

In July of 2011, while Plaintiff Shoulder Innovations, LLC had a patent application pending, Defendant Ascension Orthopedics, Inc. introduced into the market TITAN Inset Mini Glenoid products ("Titan Products"). Defendant invested over \$90,000 in research and development on the products and spent more than \$200,000 in fabricating an inventory of approximately 1,500 units.

On August 30, 2011, Plaintiff's patent issued and on September 2nd Plaintiff's counsel, via letter, invited Defendant to discuss the patent's implications at its earliest convenience. On September 13th, with Defendant not having responded, Plaintiff filed the instant action. In response, having sold an unspecified number of units, Defendant ceased sales of the Titan Products and filed an answer, denying the accusations and asserting

¹ Of the District of New Jersey, sitting by designation.

² At this motion to dismiss stage, the Court takes the following facts from the allegations in the complaint and the unopposed declarations that Defendant has submitted in response. See *MedImmune v. Genetech, Inc.*, 549 U.S. 118, 121 (2007).

counterclaims for declaratory judgment of noninfringement and invalidity of the patent.³

At some point thereafter, Plaintiff sought Defendant's consent to dismiss the entire action; Defendant refused. Plaintiff now moves this court to dismiss both its and Defendant's claims pursuant to Fed. R. Civ. P. 41(a)(2).

II.

Federal Rule of Civil Procedure 41(a)(2) holds:

Except as provided in Rule 41(a)(1),⁴ an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper. If a defendant has pleaded a counterclaim before being served with the plaintiff's motion to dismiss, the action may be dismissed over the defendant's objection only if the counterclaim can remain pending for independent adjudication.

The underlying purpose of the rule is to prevent voluntary dismissals which unfairly impact the defendant. *Buse v. Vanguard Group of Inv. Cos.*, 1994 U.S. Dist. LEXIS 3978 at 9 (E.D. Pa. 1994), citing *Paulucci v. City of Duluth*, 826 F.2d 780, 782 (8th Cir. 1987). The second sentence, limiting dismissal after the

³ Defendant asserts in its Opposition Brief that it would "still be pursuing the marketing and selling of the accused products." Lovato Declaration ¶ 5.

⁴ Fed. R. Civ. P. 41(a)(1) allows for voluntary dismissal without a court order if the plaintiff files its notice of dismissal before the opposing party serves either an answer or a motion for summary judgment. The rule also allows for dismissal pursuant to a stipulation of dismissal signed by all appearing parties. *Id.*

pleading of a counterclaim, seeks to preserve the court's jurisdiction over the parties and the counterclaim. *John Evans Sons, Inc. v. Majik-Ironers, Inc.*, 95 F.R.D. 186, 189 (E.D. Pa. 1982).

Whether a dismissal should be granted on a Rule 41(a)(2) motion lies within the sound discretion of the court. *Ockert. v. Union barge Line Corp.*, 190 F.2d 303, 304-05 (3d Cir. 1951).

III.

Plaintiff moves "pursuant to Fed. R. Civ. P. 41(a)(2) to dismiss all of its claims, and all of Defendant Ascension Orthopedics, Inc.'s counterclaims, without prejudice." Pl. Motion 1, Dkt. No. 20. Rule 41(a)(2), however, can only be used to dismiss a movant's own claims. See *id.* (allowing a plaintiff's withdrawal of its claims only if defendant's counterclaims can remain for adjudication, implying that the rule, in and of itself, cannot be used to dismiss an opposing party's claims); *Brown v. Brown*, 343 F. Supp. 2d 195, 197 (E.D.N.Y. 2004) ("As stated in Rule 41(a)(2), if a defendant's counterclaims cannot stand alone the Court is precluded from allowing the action to be dismissed."); *Environ Prods. v. Total Containment*, 1996 U.S. Dist. LEXIS 4947 (E.D. Pa.) (noting that the Third Circuit applies the same analysis for a Rule 41(a)(2) motion for voluntary dismissal as a party

seeking to amend its pleadings under Fed. R. Civ. P. 15(a)).⁵ Consequently, Plaintiff asks this Court to approve dismissal of Plaintiff's patent infringement claim while simultaneously dismissing Defendant's counterclaims.⁶ Plaintiff argues that dismissal without prejudice is appropriate because a district court is empowered with such discretion over declaratory judgment actions and Defendant's claims are presently unripe for adjudication.⁷

Defendant opposes the dismissal of its claims on the basis that a real controversy exists that requires the Court's ruling. Consequently, this Court must determine whether subject matter jurisdiction exists over Defendant's counterclaims and, if so,

⁵ Plaintiff, in its supporting brief, does not cite a single case in which 41(a)(2) is used to dismiss an opposing party's claims. In the only two cases cited therein that apply Rule 41(a)(2), the district court dismissed the opposing party's claims not pursuant to the rule, but rather on the grounds that the remaining claim was either not a "justiciable issue," *McGraw-Edison Co. v. Preformed Line Products Co.*, 362 F.2d 339, 344 (9th Cir. 1966), nor "an actual controversy," *Benitec Australia Ltd. V. Nucleonics*, 2005 U.S. Dist. LEXIS 22008 (D. Del. 2005).

⁶ Pl.'s Reply Br. 6, Fn. 2: "Shoulder Innovations' motion to dismiss its patent infringement claim is conditioned upon the Court's ruling to also dismiss Ascension's counterclaims. If the Court declines to dismiss the counterclaims, Shoulder Innovations would have no choice but to proceed with its infringement claim."

⁷ In its submissions, Plaintiff was inconsistent as to the exact grounds for dismissal: at one point it argues that Defendant's counterclaims do not present a justiciable controversy, Reply Br. at 3 ("Ascension can have no reasonable expectation that there will ever be a case or controversy with respect to the asserted patents and accused products."), while at another it contends that subject matter jurisdiction exists but a discretionary dismissal is more appropriate, see Pl. Br. at 2. Plaintiff asserted at oral argument that the Court should utilize its discretion to refrain from ruling.

whether it should exercise such jurisdiction or, conversely, dismiss the entire case without prejudice. *Wilton*, 515 U.S. at 286-87.

A. Subject Matter Jurisdiction

A claim for declaratory judgment must state an actual case or controversy. *MedImmune*, 549 U.S. at 126-27.⁸ The test for determining whether an actual case or controversy exists in a declaratory judgment action involving patents is two-pronged. *Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879 (Fed. Cir. 1985). First, the defendant's conduct must have created, on the part of the plaintiff, a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. *Benitec Australia Ltd. v. Nucleonics*, 2005 U.S. Dist. LEXIS 22008 (D. Del. 2005). Second, the plaintiff must actually have either produced the product or have prepared to produce the product. *Id.*

The party asserting the claim has the burden of establishing both prongs. *Indium Corp.*, 781 F.2d at 879. This Court finds the counterclaimant has met its burden. Ascension Orthopedics has clearly established a threat of defending against a future suit if

⁸The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction ... any court of the United States ... may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

it resumes selling its Titan Products. “[N]o express charge of infringement or threat of suit is required. Rather, a reasonable apprehension of suit may be induced by subtler conduct if that conduct rises ‘to a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent,’ to initiate an infringement action.” *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996), quoting *Shell Oil Company v. Amoco Corporation*, 970 F.2d 885, 887 (Fed. Cir. 1992).

Plaintiff brought the patent to Defendant’s attention immediately after it was issued and filed suit ten days thereafter. Plaintiff’s counsel represented to Defendant that Defendant will be sued if it reintroduces the accused products into the market. *Pompa Dec.* ¶ 2. Furthermore, Plaintiff refuses to dismiss its own claims with prejudice, insisting on maintaining the ability sue again in the future. See *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed. Cir. 2008) (recognizing as relevant to determining threat of future suit a patentee’s refusal to enter into a covenant not to sue). In light of the foregoing, Defendant has established a cognizable threat of future suit.

Defendant has also proved that they have produced the Titan Products. Defendant submits to the Court that it has approximately 1,500 units in inventory, and that such units would re-enter the market but for the instant suit. This submission satisfies the second prong of the analysis and shows to the Court that a real controversy exists, thereby granting the Court subject matter

jurisdiction over Defendant's counterclaims.

B. Discretion to Withhold Jurisdiction

The finding that subject matter jurisdiction exists over Defendant's counterclaims does not end the inquiry concerning Plaintiff's motion to dismiss. The Declaratory Judgment Act accords district courts "a unique breadth of ... discretion to decline to enter a declaratory judgment." *Wilton*, 515 U.S. at 287. Such discretion is not unfettered, however, and must be exercised in accordance with the principles of the Declaratory Judgment Act and sound judicial administration. *EMC*, 89 F.3d at 813-14. "The factors considered by the Court in exercising its discretion include, but are not limited to: (1) whether declaratory relief would clarify and settle the legal relations in issue; (2) the convenience of the parties; (3) the public interest in a settlement of the uncertainty of obligation, (4) the availability and relative convenience of other remedies; and (5) whether the declaratory judgment act is being used for 'procedural fencing,' 'forum shopping,' or as a means to provide another forum in a 'race' for res judicata." *DISH Network v. TiVo, Inc.*, 604 F. Supp. 2d 719 (D. Del. 2009), citing *Terra Nova Insurance Co. v. 900 Bar, Inc.*, 887 F.2d 1213, 1224 (3d Cir. 1989).

The instant action presents a real controversy upon which this Court should rule. Defendant has spent over \$200,000 in

manufacturing an inventory that could be reintroduced into the market with a judicial determination of noninfringement or invalidity of Plaintiff's patent. Defendant has already sold the Titan Products in accordance with a 510(k) Compliance Letter to File and represents that it will continue the costly process of obtaining FDA approval upon resolution of the instant action.⁹ Furthermore, no nefarious intent can be inferred from Defendant's prosecution of the instant claims.

Plaintiff's argument that because Defendant lacks FDA approval for the accused products its counterclaims are premature is unconvincing. Claims that FDA approval is required for a district court to rule on a declaratory judgment action have been continually rejected. *See, e.g., Infinitech v. Vitrophage, Inc.*, 842 F. Supp. 332, 337-38 (N.D. Ill. 1994); *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 397 (D. Mass. 1996); *see also BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) (holding that "[w]hile [plaintiff] may not have the present ability

⁹ The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-92, and in particular the Medical Device Amendments, 21 U.S.C. § 360c, established a federal regulatory scheme for medical devices such as the ones underlying the instant suit. The level of testing required before clearance is given for the marketing and sales of the device depends on the risks posed by the device. *Gross v. Stryker Corp.*, 2012 U.S. Dist. LEXIS 34071 at 39. Two ways in which a manufacturer can obtain clearance is through premarket approval by the U.S. Food and Drug Administration or the filing of a 510(k), whereby the manufacturer demonstrates that the new device is at least as safe and effective as one previously approved. *See United States v. Higgins*, 2011 U.S. Dist. LEXIS 140343.

to market [its product], it had embarked upon a protracted and costly process of obtaining regulatory approval. [Plaintiff's] conduct thus evinces the kind of 'concrete steps' or 'meaningful preparation' needed to establish an actual controversy under 'all the circumstances.'"). Furthermore, in the instant case, refraining from adjudication unnecessarily and inequitably forces upon Defendant the prospect of expending resources for FDA approval only to be met with the very same lawsuit once such approval is received. See *Infinitech*, 842 F. Supp. at 337 (declining to construe the Declaratory Judgment Act as "placing all of the burden and risk on those who would seek to develop new medical and surgical products" and holding that final government approval is unnecessary for a declaratory judgment claim to be cognizable).

Because of the concrete steps Defendant has taken to market its Titan Products, and the threat of suit put forward by Plaintiff, the Court finds a justiciable controversy over which this Court has jurisdiction. Furthermore, because of both the ripeness of the suit and the expenditures already incurred by the parties, the Court retains such jurisdiction. Consequently, the Court denies Plaintiff's motion to dismiss on the terms specified by Plaintiff.

IV.

In light of the foregoing, Plaintiff's motion is denied. An Order will accompany this opinion.

IT IS on this 8th day of June, 2012,

S/ Joseph E. Irenas
Joseph E. Irenas, S.U.S.D.J.

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SHOULDER INNOVATIONS, LLC,

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HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NO. 11-810
(JEI/AMD)

**ORDER DENYING PLAINTIFF'S
MOTION TO DISMISS**

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
By: Jack B. Blumenfeld
Julia Heaney
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
Counsel for Plaintiff

KNOBBE, MARTENS, OLSON & BEAR, LLP
By: Joseph F. Jennings
Joseph S. Cianfrani
2040 Main Street
Irvine, CA 92614
Counsel for Plaintiff

KNOBBE, MARTENS, OLSON & BEAR, LLP
By: Brian C. Horne
10100 Santa Monica Boulevard
Suite 1600
Los Angeles, CA 90067
Counsel for Plaintiff

BAYARD, P.A.
By: Richard D. Kirk
Stephen B. Brauerman
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
Counsel for Defendant

RITCH, EVEN, TABIN & FLANNERY
By: Mark W. Hetzler
Christine A. Pompa
120 South LaSalle Street, Suite 1600

Chicago, IL 60603
Counsel for Defendant

IRENAS, Senior District Judge¹:

This matter having appeared before the Court upon Plaintiff's Motion to Dismiss (Dkt. No. 20); the Court having considered the submissions of the parties; oral arguments having been heard June 7, 2012; and for the reasons set forth in an Opinion issued by this Court on even date herewith, and for good cause appearing;

IT IS on this 8th day of June, 2012,

ORDERED THAT:

Plaintiff's Motion to Dismiss (Dkt. No. 20) is hereby **DENIED**.

S/ Joseph E. Irenas
Joseph E. Irenas, S.U.S.D.J.

¹ Of the District of New Jersey, sitting by designation.