# IN THE UNITED STATES DISTRICT COURT
# FOR THE DISTRICT OF DELAWARE

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| TAKEDA PHARMA. U.S.A., INC.,<br>Plaintiff,<br>v.<br>MYLAN PHARMA. INC.,<br>Defendant. | No. 16-cv-987 (RGA) |

## MEMORANDUM ORDER

Defendant Mylan filed Abbreviated New Drug Application No. 29470 seeking Food and Drug Administration approval to sell a generic colchicine product for treatment of Familial Mediterranean Fever. (D.I. 1 at ¶¶ 1, 39). In late October 2016, Plaintiff Takeda filed a seventeen count complaint against Defendant on the basis of the ANDA. (D.I. 1). The complaint includes three counts with claims under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), for infringement of Plaintiff's patents covering the use of colchicine to treat FMF, twelve counts with claims under the Declaratory Judgment Act, 28 U.S.C. § 2201, for contributory infringement of Plaintiff's patents covering the use of colchicine to treat gout, and two counts with both.

In response, on December 15, 2016, Defendant filed a motion to dismiss the declaratory judgment claims under Federal Rule of Civil Procedure 12(b) for lack of

subject matter jurisdiction and for failure to state a claim of contributory infringement. (D.I. 10). That same day, Defendant also filed an answer contesting venue. (D.I. 9 at 5–6). Defendant did not, however, include an objection to venue in its Rule 12(b) motion. (*See* D.I. 10).

Defendant now seeks to press its objection to venue, spurred by the Supreme Court's opinion in *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017), overturning the Federal Circuit's interpretation of the patent venue statute. (D.I. 50). Under Rule 12, Defendant waived its objection to venue by not bringing the objection in its first filed motion to dismiss. Fed. R. Civ. P. 12(g)(2) ("a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion."); Fed. R. Civ. P. 12(h) ("A party waives any defense listed in Rule 12(b)(2)–(5) by.... omitting it from a motion in the circumstances described in Rule 12(g)(2)..."). While Defendant may have faced adverse circuit law on venue when it filed its Rule 12 motion, the objection was available to it. In fact, the Supreme Court granted certiorari in *TC Heartland* on December 14, 2016, the day before Defendant filed the Rule 12 motion. 137 S. Ct. 614 (2016).

Because Defendant waived its objection to venue, Defendant's request (D.I. 50) to dismiss or transfer the case is **DENIED**.

With that, I turn to the merits of Defendant's motion to dismiss Plaintiff's declaratory judgment claims for lack of subject matter jurisdiction. The Act requires an "actual controversy...." 28 U.S.C. § 2201(a). An "actual controversy," as referred

to in the statute, means a claim that is justiciable under Article III of the United States Constitution. *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126–27 (2007). To meet Article III's requirement, the threatened injury to Plaintiff in the absence of judicial intervention must be sufficiently imminent and real, not conjectural or hypothetical. *Summers v. Earth Island Institute*, 555 U.S. 488, 505 (2009).

Through its declaratory judgment claims, Plaintiff seeks a declaration that, if Defendant is allowed to bring a generic colchicine to market, even one indicated only for treatment of FMF, Defendant will infringe Plaintiff's gout patents under a contributory infringement theory. An entity commits contributory infringement when, with the requisite knowledge, it sells an item that is a material part of a patented process and that item is not "suitable for substantial noninfringing use...." 35 U.S.C. § 271(c).

Plaintiff's argument runs that colchicine is prescribed to treat gout 99.77 percent of the time and only .23 percent of the time to treat FMF. (D.I. 1 at ¶ 32). Plaintiff's patents cover a significant portion of the gout market (although there is a substantial part of the gout market not covered by its patents). Because of physician prescribing practices, pharmacy policy, and mandatory generic substitution laws, the primary use of a colchicine generic, even one indicated only for treatment of FMF, will be to treat gout. (*Id.* at ¶¶ 34–37).

Under *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), I have jurisdiction over Plaintiff's declaratory judgment claims. In *Glaxo*, the Federal

Circuit allowed a declaratory judgment claim for a method of manufacturing patent based on an ANDA, ancillary to Hatch-Waxman litigation. *Id.* That case is not meaningfully different from this one. While there is an additional contingency here, off-label prescribing practices, there is no dispute that doctors will prescribe, and pharmacies will fill, Defendant's generic for use to treat gout.

Even though I can exercise jurisdiction over Plaintiff's declaratory judgment claims, I have discretion to decline to do so. *Id.* at 1570 ("[T]he exercise of jurisdiction over [a declaratory judgment] action is within the discretion of the district court."). I decline jurisdiction over Plaintiff's declaratory judgment claims for four reasons.

For one, the addition of gout claims from fourteen patents will unnecessarily complicate resolution of the case. The FMF claims from the five patents implicated in the Hatch-Waxman counts represent a current controversy. With these claims alone, it is a substantial case. Including the gout claims, which are only tangentially related to the FMF claims, would more than triple the patents in the case.

For two, while *Glaxo* dictates that jurisdiction exists here, Plaintiff's claimed injury is still fairly conjectural. For Plaintiff to suffer the injury it fears, three contingencies would have to occur. First, I would have to decide against Plaintiff on its FMF patents, finding either that Defendant's ANDA, which by law must match the NDA those patents cover, does not infringe Plaintiff's patents or that these presumptively valid patents are invalid. Second, the FDA would have to approve the ANDA. Third, doctors would have to prescribe the generic for an off-label use.

For three, the law provides an adequate remedy to Plaintiff even without the declaratory judgment act. If Plaintiff's allegations are correct, it will have a good case for induced infringement once Defendant starts to offer generic colchicine for sale. Plaintiff may be able to avail itself of the remedies for intentional infringement.

For four, Plaintiff's claim is, by design, a weak case for contributory infringement at best. As is necessary to file an ANDA with a carve-out, Plaintiff's ANDA implicates an FDA approved use, treatment of FMF. It is hard to see how an FDA approved use would not qualify as a substantial non-infringing use. The better statutory framework for Plaintiff's claim is induced infringement; but, as Plaintiff concedes, it is premature for adjudication of an induced infringement claim.

For these reasons, I am declining jurisdiction over Plaintiff's declaratory judgment counts. Defendant's motion to dismiss (D.I. 10) the declaratory judgment claims in counts IV and V and to dismiss counts VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII is **GRANTED**.

**IT IS SO ORDERED** this 3 day of August 2017.

United States District Judge