IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA, N.V., JANSSEN SCIENCES IRELAND UC, GILEAD SCIENCES, INC., and GILEAD SCIENCES IRELAND UC,	)	
Plaintiffs,	)	
v.	)	Civ. No. 15-760-SLR/SRF
MYLAN PHARMACEUTICALS INC. and MYLAN INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 29th day of September, 2016, having reviewed the objections filed by defendants to Magistrate Judge Fallon's Report and Recommendation dated July 28, 2016, as well as plaintiffs' response thereto;

IT IS ORDERED that the Report and Recommendation (D.I. 96) will be affirmed and the objections thereto (D.I. 110) overruled, for the following reasons:

1. **Legal standard.** A district judge is charged with conducting a de novo review of a magistrate judge's report and recommendation to which specific, written objections are made. 28 U.S.C. § 636(b)(1); *see also Sample v. Diecks*, 885 F.2d 1099, 1106 n.3 (3d Cir. 1989). The district judge may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1). Although review is de novo, the district judge, in exercising her sound discretion, is

permitted to rely on the recommendations of the magistrate judge to the extent she deems proper. *United States v. Raddatz*, 447 U.S. 667, 676-677 (1980); *Goney v. Clark*, 749 F.2d 5, 7 (3d Cir. 1984).

2. **Motion to dismiss.** Judge Fallon explained, in her well-written opinion, that exercising specific personal jurisdiction over defendants in this case is proper under the minimum-contacts and fairness requirements of due process and Delaware's long-arm statute, consistent with the controlling decision issued by the Federal Circuit in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). Although defendants continue to disagree with this analysis, I find no legal error therein, and no reason to repeat the same reasoning as did Judge Fallon.

3. Judge Fallon also correctly found that plaintiffs satisfied their burden of making a prima facie showing that defendant Mylan Inc. is subject to personal jurisdiction under the agency theory. *See Electronics for Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003); *Celgard, LLC v. SK Innovation Co., Ltd.*, 792 F.3d 1373, 1378 (Fed. Cir. 2015). Defendants' objections go to issues of fact that are better addressed after discovery has been taken.[1] Because I find no error in Judge Fallon's conclusion in this regard, I also find no error in Judge Fallon's venue analysis.

4. **Motion to strike.** Defendants argue that Judge Fallon erred by denying defendants' motion to strike and sever plaintiffs' counterclaims charging defendants with infringing plaintiffs' process patents. The counterclaims concern the manufacture

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[1]The court notes that defendants refused to provide basic jurisdictional discovery in this case; consequently, plaintiffs relied on "relevant, albeit redacted, deposition testimony of defendants' corporate designee in another ANDA case." (D.I. 114 at 8)

of an intermediate compound (PBN-II) made by a third party in India, which compound is used by that third party in the synthesis of another intermediate compound (PBN-III), which is then used by a Mylan entity to make one of three active pharmaceutical ingredients (rilpivirine) found in the ANDA product to be imported by defendant Mylan Pharmaceuticals, Inc.. (*See* D.I. 110 at 10) According to defendants, the counterclaim patents "are too far removed from the core issues in this Hatch-Waxman case to be properly litigated here." (*Id.*)

5. Judge Fallon correctly concluded that plaintiffs may join to the ANDA litigation (brought pursuant to 35 U.S.C. § 271(e)(4)) a declaratory judgment action (brought pursuant to 28 U.S.C. § 2201 and 35 U.S.C. § 271(g)) in order to prevent defendants' importation or sale of a product made by the processes disclosed in plaintiffs' counterclaim process patents. In the first instance, consistent with the language of the statute,[2] the act of infringement is the importation of a product made by a process patented in the United States, not the act of manufacturing the product. Moreover, and as noted in the papers, defendants stipulated to the addition of similar § 271(g) claims disclosing "processes useful for the preparation of [another] essential component of the rilpivirine API." (D.I. 33 at ¶ 44) To the extent defendants are arguing a material-change defense, Judge Fallon correctly found that such a defense presents a factual dispute not for resolution on the pleadings. *See, e.g., Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009) (addressing the material-change defense

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[2]"Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer. . . ." 35 U.S.C. § 271(g).

on appeal from post-trial decision).

THEREFORE, IT IS FURTHER ORDERED that:

6. Defendants' motion to dismiss (D.I. 40) is denied.

7. Defendants' motion to strike and sever the two PBN-II process patents (D.I. 57) is denied.

United States District Judge