IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| NOVARTIS PHARMACEUTICALS CORP.,<br>Plaintiff,<br>v.<br>PAR PHARMACEUTICAL INC.,<br>Defendant. | Civil Action No. 14-1289-RGA |
| NOVARTIS PHARMACEUTICALS CORP.,<br>Plaintiff,<br>v.<br>PAR PHARMACEUTICAL INC.,<br>Defendant. | Civil Action No. 14-1494-RGA |
| NOVARTIS PHARMACEUTICALS CORP.,<br>Plaintiff,<br>v.<br>PAR PHARMACEUTICAL INC.,<br>Defendant. | Civil Action No. 15-0078-RGA |

MEMORANDUM ORDER

Currently pending before the Court is Plaintiff's Motion for Estoppel under 35 U.S.C. § 315(e)(2). (C.A. No. 14-1289, D.I. 193; C.A. No. 14-1494, D.I. 120; C.A. No. 15-0078, D.I.

120).[1] Defendant Par Pharmaceutical has indicated that it "takes no position" on the estoppel issue. (D.I. 195). Thus, Plaintiff's motion for estoppel is unopposed. However, as Plaintiff bears the burden of demonstrating that estoppel applies under 35 U.S.C. § 315(e)(2), I have reviewed Plaintiff's brief and the record to ensure that Plaintiff has met its burden.

## I. BACKGROUND

Plaintiff Novartis Pharmaceuticals filed three suits against Defendant Par Pharmaceutical on October 10, 2014 (C.A. No. 14-1289, D.I. 1), December 18, 2014 (C.A. No. 14-1494, D.I. 1), and January 23, 2015, (C.A. No. 15-78, D.I. 1), respectively. Plaintiff also filed related suits against Defendants Breckenridge and West-Ward. (D.I. 193 at 5 n.4). The parties agreed that the validity of U.S. Patent No. 5,665,772 ("the '772 patent") would be tried only once. (D.I. 139 at 3-4). Before trial, Defendants conceded that their proposed products meet all limitations of the '772 patent. (D.I. 152 at 34). At trial, Defendants challenged the validity of claims 1-3, 7, and 10 of the '772 patent on obviousness grounds, citing twenty-seven pieces of prior art. (D.I. 139 at 6).

While litigation was pending, Defendant Par challenged claims 1-3 and 8-10 of the '772 patent in an inter partes review ("IPR") proceeding. (IPR2016-00084, "the Par I IPR"). The Patent Trial and Appeal Board ("PTAB") instituted the Par I IPR on April 29, 2016. After institution of the Par I IPR, Defendants filed four additional IPR petitions challenging the '772 patent along with motions to join the Par I IPR. (IPR2016-01059, IPR2016-01023, IPR 2016-01103, IPR2016-01102). On October 27, 2016, the PTAB instituted the two IPRs which challenged claims 1-3 and 8-10 and joined them with the Par I IPR. (D.I. 139 at 6-7). The PTAB declined to institute and join IPRs challenging claim 7 of the '772 patent because Defendant Par, failed to explain why claim 7 was omitted from the Par I petition. (*Id.*).

[1] All docket item references in this order refer to C.A. No. 14-1289 unless otherwise specified.

On March 28, 2017, I issued a trial opinion, determining that the asserted claims of the '772 patent were invalid for obviousness-type double patenting. (D.I. 169 at 32). I did not address Defendants' obviousness defenses or counterclaims. (*Id.*). Defendants appealed. On January 11, 2018, while the appeal was pending on the obviousness-type double patenting decision, the PTAB issued a final written decision in the Par I IPR upholding the patentability of claims 1-3 and 8-10 of the '772 patent. *Par Pharm. Inc. v. Novartis AG*, 2018 WL 389192, at *1 (P.T.A.B. Jan. 11, 2018). The Federal Circuit later reversed the obviousness-type double patenting decision. *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1367 (Fed. Cir. 2018). After the Federal Circuit issued its mandate in the appeal, I asked the parties in these cases to file a status report summarizing the issues that still needed to be addressed in the suits relating to the '772 patent. (D.I. 187).

At that time, Plaintiff raised the possibility that 35 U.S.C. § 315(e)(2) would estop Defendants' obviousness defenses and counterclaims based upon the final written decision of the Par I IPR. (D.I. 191 at 2-3). Defendant Breckenridge raised several objections to the application of IPR estoppel and asserted that the Court should resolve the obviousness defenses/counterclaims at the same time as estoppel. (*Id.* at 3-4). On March 1, 2019, I issued an order requesting briefing by Plaintiff on estoppel and joint briefing from Defendants on obviousness. (D.I. 192). After that order, the suits including Defendants Breckenridge and West-Ward were dismissed by joint stipulation. (C.A. No. 14-1196, D.I. 221; C.A. No. 16-0431, D.I. 99; C.A. No. 14-1043, D.I. 212). Plaintiff has filed an opening brief moving for estoppel of Defendant Par's obviousness counterclaims. (D.I. 193). Defendant Par has indicated that it "takes no position" on the estoppel issue. (D.I. 195). Defendant Par also has not filed any briefing on the obviousness issue in

response to my March 1 order, stating instead that it believes that a decision can be rendered based upon the briefing and testimony submitted to date.[2] (*Id.*).

## II. Standard for IPR Estoppel Under 35 U.S.C. § 315(e)(2)

35 U.S.C. § 315(e)(2) provides,

> The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a) . . . may not assert in either a civil action arising in whole or in part under section 1338 of title 28 . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter parties review.

The Federal Circuit has not directly addressed the issue of whether estoppel applies to prior art references that were not raised in the IPR proceeding. However, the majority of District Courts have determined that IPR estoppel applies to any prior art that reasonably could have been raised, even if not actually raised in the IPR proceeding. *See, e.g.*, *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, 322 F. Supp. 3d 537, 541 (D. Del. 2018) (citing *Bio-Rad Labs., Inc. v. 10X Genomics, Inc.*, C.A. No. 15-152, D.I. 228 at 28:17-29:14 (D. Del. Sept. 26, 2017)); *Parallel Networks Licensing, LLC v. IBM Corp.*, 2017 WL 1045912, at *11-12, (D. Del. Feb. 22, 2017); *Am Tech. Ceramics Corp. v. Presidio Components, Inc.*, 2019 WL 365709, at *2, 4-5 (E.D.N.Y. Jan. 30, 2019); *Milwaukee Electric Tool Corp. v. Snap-On Inc.*, 271 F. Supp. 3d 990, 1029-30 (E.D. Wisc. 2017); *Network-1 Techs., Inc. v. Alcatel-Lucent USA, Inc.*, No. 6:11-cv-00492-RWS, 2017 U.S. Dist. LEXIS 178857, at *6-7 (E.D. Tex. Oct. 27, 2017).

As I have stated previously, the general purpose of the statute as well as the statutory language indicate that the most plausible interpretation is that any prior art that the IPR petitioner could have raised in the proceeding is estopped if there is a final written decision from the PTAB

[2] I do note that Defendant Breckenridge was the party who requested further briefing on the obviousness issue, and that Defendant Par has maintained this position since the case was remanded from the Federal Circuit. (D.I. 191 at 3-4).

that the challenged claims are valid. *See Bio-Rad*, C.A. No. 15-152, D.I. 228 at 28:17-29:14. Prior art "reasonably could have been raised" when "a skilled searcher conducting a diligent search reasonably could have been expected to discover" the prior art. *See, e.g.*, Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). Moreover, one of the policy objectives behind the introduction of IPR proceedings was an intention to conserve judicial resources. *Am Tech.*, 2019 WL 365709, at *2. Allowing an IPR petitioner to have two bites at the apple by holding back certain obviousness combinations runs counter to both the clear language and purpose behind § 315. *Parallel Networks*, 2017 WL 1045912, at *12.

Defendant Breckenridge also raised an objection to the application of IPR estoppel after the district court has held trial. (D.I. 191 at 3-4). I do not think the application of IPR estoppel is dependent on the order in which certain events occur. This is a matter of first impression. While previously raised in *Senju Pharmaceutical Co. v. Lupin Ltd.*, C.A. No. 14-667 (D.N.J.), the parties settled before the Court could determine the issue. *Senju Pharm.*, C.A. No. 14-667, D.I. 301 (D.N.J. Aug. 1, 2016), D.I. 302 (D.N.J. Aug. 2, 2016), D.I. 314 (D.N.J. Aug. 29, 2016).

The plain language of the statute does not indicate that Congress intended for there to be a time limitation upon the estoppel effect of a final written decision of an IPR. The parties in *Senju* focused upon the use of the terms "request" and "maintain" in § 315(e)(1) and the term "assert" in § 315(e)(2). *Senju Pharm.*, C.A. No. 14-667, D.I. 302 at 1-3. It appears to me that the differences in statutory language is a result of the forum in which the estoppel occurs, rather than evidence that Congress intended IPR estoppel to be limited to time before trial is completed. Section (e)(1) describes the estoppel effect of a final written decision on other PTAB proceedings. As this section deals with administrative proceedings, the language is appropriately directed to that context. Thus, § 315(e)(1) states that after a final written decision is issued, the petitioner may not "request or

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