IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD., Plaintiffs, v. SAMSUNG BIOEPIS CO. LTD., Defendant.	Civil Action No. 24-5-GBW Unsealed on 5/10/24

MEMORANDUM ORDER

Alexion Pharmaceuticals Inc. and Alexion Pharma International Operations Ltd. (collectively, "Alexion") sued Samsung Bioepis Co. Ltd. ("Samsung") alleging patent infringement under the Biologics Price Competition and Innovation Act ("BPCIA"). D.I. 1. Alexion has moved for a preliminary injunction. D.I. 16; *see* 42 U.S.C. § 262(*l*)(8)(A). The Court has reviewed the briefing (D.I. 17, 38, 49) and finds that oral argument is not necessary. The Court denies Alexion's motion for a preliminary injunction.

I. BACKGROUND

SOLIRIS (eculizumab) is a monoclonal antibody indicated for the treatment of rare blood disease, including paroxysymal nocturnal hemoglobinuria ("PNH") and atypical hemolytic uremic syndrome ("aHUS"). SOLIRIS works by binding with high affinity and specificity to an epitope of the C5 protein, thus preventing cleavage of that protein. Without SOLIRIS, the body cleaves C5 into C5a and C5b, which leads to downstream effects in the complement pathway, including hemolysis in PNH patients and thrombotic microangiopathy in aHUS patients.

Alexion has asserted six patents and seeks injunctive relief due to the infringement of two claims: claim 1 of U.S. Patent No. 9,447,176 ("the '176 patent") and claim 1 of U.S. Patent No. 10,590,189 ("the '189 patent") (collectively, the "PI Claims"). Claim 1 of the '189 patent recites a method of treating PNH (the "PNH claim"), while claim 1 of the '176 patent recites a method of treating aHUS (the "aHUS claim").

Samsung requested *inter partes* review (IPR) of the '189 patent. The Patent Trial and Appeal Board ("PTAB") instituted IPR. Samsung sent Alexion a notice that it expected to receive FDA approval of its SOLIRIS biosimilar, SB12, in the first half of 2024. D.I. 19-1 at 96. Samsung also provided a Notice of Commercial Marketing notifying Alexion that it would not launch SB12 before January 3, 2024 (180 days from the letter). *Id.* Alexion filed this suit on January 3, 2024, and filed for preliminary injunction on February 12, 2024.

II. LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" that should be granted only in "limited circumstances." *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). The decision to grant or deny preliminary injunctive relief lies within the sound discretion of the district court. *See Greater Phila. Chamber of Com. v. City of Phila.*, 949 F.3d 116, 133 (3d Cir. 2020). To obtain a preliminary injunction, the moving party must establish: (1) a likelihood of success on the merits; (2) irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the non-moving party; and (4) that the public interest favors such relief. *Kos Pharms.*, 369 F.3d at 708.

The first two factors—likelihood of success on the merits and irreparable harm—are "gateway factors" that the moving party must establish to obtain relief. *Reilly v. City of*

Harrisburg, 858 F.3d 173, 179 (3d Cir. 2017); *Greater Phila. Chamber of Com.*, 949 F.3d at 133. Unless the movant meets its burden on these two factors, a preliminary injunction is not warranted, regardless of whether the Court proceeds to consider the balance of equities and the public interest. *Reilly*, 858 F.3d at 179.

A patent holder seeking a preliminary injunction "bears the burden of establishing likelihood of success on the merits with respect to the patent's validity." *See Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007). If the accused infringer presents an invalidity defense, at the preliminary injunction stage it is the patentee "who must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009). An accused infringer need only raise a "substantial question" of invalidity to defeat a preliminary injunction. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

III. DISCUSSION

The Court finds that Alexion has not shown that it is likely to succeed on the merits of its claims, because it has not established a likelihood of success on the merits with respect to the validity of either of the PI claims.

A. There is a Substantial Question of Validity Regarding the PNH Claim.

The PTAB has instituted IPR against the '189 patent. In doing so, it found that there was a "reasonable likelihood of showing at trial that claims 1-8 [of the '189 patent] are unpatentable as obvious." D.I. 38-3 at 2, 67. District courts must consider the "current posture of . . . proceedings at the PTO when evaluating [a plaintiff's] likelihood of success on the merits." *Procter & Gamble*

Co. v. Kraft Foods Glob., 549 F.3d 842, 847–48 (Fed. Cir. 2008) (addressing pre-AIA *inter partes* reexamination). Numerous courts have found that the institution of IPR, by itself, raises a substantial question of validity. *See, e.g.*, *Murata Mach. USA, Inc. v. Daifuku Co., Ltd.*, 2016 WL 4287040, at *2 (D. Utah Aug. 15, 2016); *Adidas Am., Inc. v. Skechers USA, Inc.*, No. 3:16-CV-1400-SI, 2017 WL 2604310, at *6 (D. Or. June 12, 2017); *see DNA Genotek Inc. v. Spectrum Sols. L.L.C.*, No. 16-CV-1544 JLS (NLS), 2016 WL 8738225, at *3 (S.D. Cal. Oct. 6, 2016) (finding that even the institution of IPR on a related patent raises a substantial question of validity).

The Court finds that the PTAB's institution of IPR against the '189 patent raises a substantial question of validity. In FY 2023, over 77% of instituted claims were cancelled in a final written decision.[1] D.I. 38, Ex. 10. Here, the PTAB engaged in an extensive analysis of the validity of the PNH claim and found that there was a reasonable likelihood that the claim was invalid. Accordingly, because Alexion has not presented compelling evidence that the PTAB instituted that IPR in error, the Court finds that the PTAB's institution of an IPR against the '189 patent raises a substantial question of validity as to the PNH claim.

Alexion argues that Samsung is unable to raise a substantial question of validity because Samsung would be estopped from asserting the invalidity defenses it raises during IPR at trial. D.I. 49 at 2-3. This argument oddly suggests that the Court should grant an injunction against nearly every party that achieves success at instituting an IPR if that party intends to present only an invalidity defense at trial, as that party would be unable to raise those defenses at trial. Moreover, Alexion's argument conflicts with *Procter & Gamble*, which requires district courts to

[1] Alexion points out that this ignores the IPRs where the patentee disclaimed subject matter, or no Final Written Decision was issued. D.I. 49 at 3-4. However, this is the relevant statistic, since neither of those scenarios is applicable to the case-in-suit.

consider the potential outcomes of parallel proceedings, despite the existence of estoppel for pre-AIA *inter partes* reexaminations. *See* 35 U.S.C. § 315(c) (pre-AIA). Thus, the Court declines to find that IPR estoppel prevents the PTAB's institution of IPR from raising a substantial question of validity and finds that Samsung has raised a substantial question of validity with respect to the PNH claim.

B. There is a Substantial Question of Validity Regarding the aHUS Claim.

Samsung raises two invalidity defenses with respect to the aHUS claim. First, Samsung argues that the aHUS claim is obvious over a combination of Noris (2005) and the SOLIRIS label (2007). Second, Samsung argues that the aHUS claim is anticipated by Chatelet (2008) because the aHUS claim is not entitled to a priority date before November 10, 2009. The Court finds that each of these invalidity theories raises a substantial question of validity.

Samsung contends that a person of ordinary skill in the art would have been motivated to use eculizumab to treat aHUS based on a combination of Noris (2005) and SOLIRIS (2007). The SOLIRIS label (2007) provides a dosing schedule of eculizumab for an FDA-approved treatment for another complement hyperactivation disease (PNH). Bissler Decl. ¶¶ 48-56, 125-26. Noris (2005) is a review article that shows that people of ordinary skill in the art, as of the priority date of the patent, recognized that PNH and aHUS are hemolytic disorders caused by hyperactivation of the complement system. D.I. 41 (Bissler Decl.) ¶¶ 57-64, 108-111. Noris (2005) further notes that eculizumab is a monoclonal antibody "directed against C5 that inhibit[s] the activation of terminal complement components" and indicates "hope[]" that it (and two other compounds) could treat aHUS patients, "once available to the market." D.I. 38, Ex. 3 at 1044. Samsung argues that a person of ordinary skill in the art would have been motivated to combine those references to treat

aHUS using eculizumab given Noris's express suggestion to do so, and SOLIRIS's known safety. Bissler Decl. ¶¶ 120-23.

Alexion disagrees, and argues that a person of ordinary skill in the art would not have a reasonable expectation of success in combining Noris (2005) and SOLIRIS (2007). Alexion notes that the other two therapies listed in Noris (2005) have never been clinically approved for the treatment of aHUS. D.I. 51 (Blasco Decl.) ¶ 75. Alexion also argues that "hope that a potentially promising drug will" work is not enough. *See OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) ("[G]iven a 99.5% failure rate and no efficacy data or any other reliable indicator of success, the only reasonable expectation at the time of the invention was failure, not success.").

The Court, however, finds that *OSI Pharms* is distinguishable. A person of ordinary skill in the art in the instant case would have reason to expect successful treatment of aHUS using eculizumab because the mechanism of that disease, the C5 pathway, has been identified. In contrast, a person of ordinary skill in the art in *OSI Pharms* would not have expected any particular one of the 1,630 drug compounds identified to successfully treat the disease at issue because of, *inter alia*, "the 99.5% failure rate." *Id.* Thus, unlike in *OSI Pharms.*, Samsung has presented sufficient evidence, at this stage, to suggest that a person of ordinary skill in the art would have known that SOLIRIS was clinically safe and possessed a reasonable likelihood of successfully treating aHUS by inhibiting the C5 pathway. Bissler Decl. ¶¶ 125-27. Moreover, the failure of the other two therapies listed in Noris (2005) is immaterial: that they were not FDA approved as clinically safe only gives a person of ordinary skill in the art more reason to try the therapy that was known to be safe, and explicitly suggested by Noris (2005). *See Application of Morin*, 405 F.2d 1313, 1315 (C.C.P.A. 1969) (a patent is not rendered non-obvious if there are two alternatives

available, and only one works). While there are many factual questions related to whether Samsung's proposed combination would have been obvious to a person of ordinary skill in the art, the Court finds that Samsung has at least raised a substantial question of validity as to the aHUS claim.[2]

IV. CONCLUSION

The Court has found that each of the PI claims faces a substantial question of validity. Thus, Alexion has failed to demonstrate a likelihood of success. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997). Accordingly, the Court denies the extraordinary relief of a preliminary injunction, without reaching the other factors. *Reilly*, 858 F.3d at 179.

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Therefore, at Wilmington this 6th day of May 2024, **IT IS HEREBY ORDERED** that Motion for Preliminary Injunction (D.I. 16) is **DENIED**.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

[2] The Court does not reach Samsung's other invalidity theory (Chatelet (2008)), except to note that the existence of a second invalidity theory strengthens the Court's conclusion that there is a substantial question of validity.