IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD.,	)	
Plaintiffs,	)	C.A. No. 24-5-GBW
v.	)	[redacted]
SAMSUNG BIOEPIS CO. LTD.,	)	
Defendant.	)	

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL AND TEMPORARY RESTRAINING ORDER PENDING RESOLUTION OF THIS MOTION

Dated: May 17, 2024

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I. INTRODUCTION

Plaintiffs Alexion Pharmaceuticals, Inc. and Alexion Pharma International Operations Ltd. (collectively, "Alexion") respectfully submit that the Court's Memorandum Order (D.I. 57) denying Plaintiffs' Motion for Preliminary Injunction (D.I. 16), contains several legal errors. Alexion filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit on May 14, 2024 (D.I. 58), and intend to expedite those proceedings. To maintain the status quo during the appeal, Alexion respectfully requests that this Court issue an Order pursuant to Federal Rule of Civil Procedure 62(d) and 35 U.S.C. § 283 granting an injunction preventing Samsung from launching its proposed biosimilar product at risk before the appeal is concluded.

Alexion also respectfully requests, pursuant to Federal Rule of Civil Procedure 65(b), a temporary restraining order enjoining Samsung from that same conduct pending resolution of this emergency motion. If denied, Alexion alternatively requests a temporary restraining order enjoining Samsung while Alexion seeks an injunction from the Federal Circuit pursuant to Federal Rule of Appellate Procedure 8(a).

II. LEGAL STANDARD

While an appeal is pending, a district court may grant an injunction on terms that secure the opposing party's rights. *See* Fed. R. Civ. P. 62(d). In determining whether to grant an injunction, courts consider four factors: whether (1) the movant has made a strong showing it is likely to succeed on the merits; (2) the movant will be irreparably injured absent an injunction; (3) an injunction will not substantially injure the non-movant (the balance of hardships); and (4) the public interest favors an injunction. *See Hilton* v. *Braunskill*, 481 U.S. 770, 776 (1987);

Eli Lilly & Co. v. *Actavis Elizabeth LLC*, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010).[1] The first factor favors injunctive relief if the movant shows either "a strong likelihood of success on the merits" on appeal or "a substantial case on the merits provided that the harm factors militate in its favor." *Eli Lilly & Co.*, 2010 WL 3374123, at *1. Evaluation of the factors is not a rigid exercise, and each factor need not be treated equally. *Standard Havens Prods., Inc.* v. *Gencor Indus., Inc.*, 897 F.2d 511, 512–13 (Fed. Cir. 1990).

Courts may issue injunctions pending appeal to prevent launch of generic drugs. *See, e.g.*, *Astrazeneca LP* v. *Breath Ltd.*, 2013 WL 9853383, at *1 (Fed. Cir. May 24, 2013); *In re Cyclobenzaprine*, 2011 WL 1980610, at *1.

III. SUMMARY OF THE ARGUMENT

[redacted] An injunction to maintain the status quo pending resolution of Alexion's appeal is appropriate because:

(1) Alexion can make a strong showing that it is likely to succeed on the merits. Among other errors, the Memorandum Order incorrectly found that Samsung raised a substantial question of validity as to each of the Preliminary Injunction ("PI") claims; failed to consider whether Samsung's invalidity arguments will meet the clear and convincing standard required at trial; and refused to properly evaluate Alexion's IPR statutory estoppel argument.

[1] The same four-factor analysis applies to a request for a temporary restraining order pursuant to Rule 65(b). *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 2011 WL 1980610, at *1 (D. Del. May 20, 2011).

Although the Memorandum Order does not address the remaining preliminary injunction factors, Alexion satisfied its burden as to these factors in the original briefing because:

(2) Alexion will suffer irreparable harm that cannot be adequately compensated by money damages if Samsung is not enjoined. If Samsung launches its biosimilar product, Alexion will lose significant dollar sales and market share; suffer net price erosion; experience significant disruption to their workforces; lose research and development efforts into additional uses for SOLIRIS®; and will incur harm to their reputation and goodwill that cannot be reversed even if Samsung's product is later withdrawn from the market.

(3) The balance of hardships favors Alexion. Alexion will suffer irreversible harm if Samsung launches its generic product, whereas Samsung, who has not yet marketed that product, will suffer little, if any, harm if an injunction is granted.

(4) The public interest weighs in Alexion's favor. Protecting valid patents incentivizes innovators, like Alexion, to make substantial investments in developing pharmaceuticals.

IV. ARGUMENT

A. Alexion Has a Strong Likelihood of Success on Appeal

The Federal Circuit has explained that the trial court's decision process for determining whether a "substantial question" of invalidity has been raised at the preliminary injunction stage "requires the court to assess the potential of a clear and convincing showing in the future." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1380 (Fed. Cir. 2009) (internal quotation marks omitted). Here, it does not appear that the Court considered whether any of Samsung's arguments will rise to the clear and convincing standard "at trial" as required. *Id.* at 1379-1380. If the Court had considered Samsung's arguments according to the proper burden and timeframe, it would have found that Samsung failed to raise any substantial questions as to the validity of the PI claims.

1. The Memorandum Order Incorrectly Finds a Substantial Question of Validity Regarding Claim 1 of the '189 Patent

The Memorandum Order attributes undue weight to the '189 IPR institution decision and fails to recognize that IPR institution decisions are preliminary, requiring far less than clear and convincing evidence. *See* 35 U.S.C. § 314(a) (institution of an IPR requires only a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition"). Moreover, PTAB decisions are not generally binding on district courts. *See, e.g.,Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 n.7 (Fed. Cir. 2017) ("The PTAB's [final written] decision is not binding on this court, and … it does not persuade us that the district court abused its discretion in granting the preliminary injunction."); *see also Liqwd, Inc. v. L'Oreal USA, Inc.* 2018 WL 11189633, at *3 (D. Del. 2018) ("The PTAB's decision invalidating the '419 patent is not binding on the court"); *Genuine Enabling Tech., LLC v. Sony Corp.*, 2020 WL 1140910, at *7 (D. Del. 2020) ("The PTAB's construction is not binding on this Court").

Further, the Memorandum Order does not assess Samsung's inability to make a clear and convincing showing as to the invalidity of the '189 patent ***at trial***, where Samsung will be estopped by statute from relying on its IPR arguments. Without those arguments at its disposal, and without having raised any other arguments for the invalidity of claim 1 of the '189 patent, Samsung cannot meet the clear and convincing burden for invalidating claim 1 of the '189 patent at trial. Alexion's estoppel argument raises a serious question of law that the Memorandum Order failed to fully address: The IPR estoppel statute supersedes judge-made law regarding the equities at the preliminary injunction stage. Although the Court concludes that Alexion "oddly suggests" Samsung should be enjoined based on IPR estoppel (D.I. 57 at 4), this suggestion is the logical consequence of the IPR estoppel statute and preliminary injunction case law requiring a court to consider what could potentially happen ***at trial***.

Before this action was filed, Samsung filed IPR petitions against five of the six patents asserted against Samsung in Alexion's Complaint (D.I. 1).[2] In December 2023, the Board instituted trial in Samsung's five IPRs. Final written decisions in those proceedings should thus issue in or around December 2024, which will be before a trial can occur in this litigation.

After a final written decision issues in the five IPRs, Samsung will be estopped from asserting in this litigation all the invalidity defenses it "raised or reasonably could have raised" in those IPRs. 35 U.S.C. § 315(e)(2); *Intuitive Surg., Inc.* v. *Ethicon LLC*, 25 F.4th 1035, 1041 (Fed. Cir. 2022) ("[E]stoppel is triggered when an IPR proceeding results in a final written decision."). Estoppel applies whether or not Samsung's challenges at the PTAB are successful (which Alexion contends they will not be). Moreover, even if Samsung were to receive a favorable final written decision from the Board in December 2024 (which it will not), this litigation will proceed to trial on all remaining issues, including infringement, for three reasons: (1) trial will occur before a final decision on appeal in the IPRs; (2) "the Board's final written decision does not cancel claims; the claims are cancelled when the Director issues a certificate confirming unpatentability, which occurs only after 'the time for appeal has expired or any appeal has terminated,'" *United Therapeutics Corp.* v. *Liquidia Tech.*, 74 F.4th 1360, 1372 (Fed. Cir. 2023) *citing* 35 U.S.C. § 318(b); and (3) "an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights," *id. citing XY, LLC* v. *Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018). Given that a trial will occur ***in this litigation*** before any decision on appeal in the IPRs, but after the Board's final written decisions, Samsung will be estopped from relying on the invalidity defenses it raised or reasonably could have raised in those

[2] Samsung did not challenge the validity of the '176 patent before the PTAB. Nor did Samsung's Answer and Counterclaims (D.I. 11) provide any specific allegations of invalidity of that patent.

IPRs during trial ***in this litigation***. And trial in this litigation is the relevant inquiry for determining likelihood of success on the merits for purposes of a preliminary injunction. *See Abbott Lab'ys v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008) ("(1) likelihood of success on the merits ***of the underlying litigation***") (emphasis added). The upshot here is that all of Samsung's invalidity defenses that it raised or reasonably could have raised in its IPRs have no legal bearing on these preliminary injunction proceedings.[3]

Nor will Alexion be collaterally estopped from continuing to assert its infringement positions concerning the five patents challenged by IPR in this litigation, which holds true even in the unlikely event of a victory by Samsung at the PTAB in a final written decision. "Federal Circuit case law suggests that an IPR decision does not have preclusive effect until that decision is either affirmed or the parties waive their appeal rights." *TrustID, Inc. v. Next Caller Inc.*, C.A. No. 18-172 (MN), 2021 WL 3015280, at *3 (D. Del. July 6, 2021) (citing four decisions by the Federal Circuit). Though "allowing Plaintiff to proceed at trial on claims that have been found by the PTAB to be invalid while at the same time preventing Defendant from asserting prior art defenses against these claims based on estoppel under § 315(e)(2) seems counterintuitive," "it is a permissible result that follows from the statute and the relevant case law." *Id.* at *4.

For these reasons, Alexion is likely to succeed on appeal with respect to this Court's finding of a substantial question of validity as to the '189 patent claim.

2. The Memorandum Order Erroneously Finds a Substantial Question of Validity Regarding Claim 1 of the '176 Patent

Samsung raises two invalidity arguments with respect to claim 1 of the '176 patent. The Memorandum Order erroneously "finds that each of these theories raises a substantial question of

[3] Alexion acknowledges that estoppel under Section 315 will apply only to the '189 patent and the other four patents challenged by Samsung by IPR. It will not apply to the '176 patent, which Samsung did not challenge by IPR.

invalidity." D.I. 57 at 5. First, Samsung argues that the claim is obvious over the combination of Noris (2005) and the SOLIRIS® label (2007). As the Memorandum Order acknowledges, Noris (2005) indicates a "hope[]" that eculizumab could be used to treat aHUS patients. D.I. 57 at 5. But mere "hope" that eculizumab would be useful in treating aHUS patients, could in no way satisfy the clear and convincing standard at trial, and therefore does not raise a "substantial question."

A POSA would not have had a reasonable expectation of success in using eculizumab to treat aHUS, solely because of the drug's success in treating PNH. A reasonable expectation of success is a "higher bar" than "hope" or "cautious optimism." *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 20-804-RGA, 2023 WL 4175334 (D. Del. June 26, 2023) (finding non-obviousness due to no reasonable expectation of success where prior art was merely "hope[ful]" and "optimis[tic]" that a drug would be effective in treating one cancer based on previous success in treating a related cancer).

Samsung provides only attorney argument to read a "reasonable expectation of success" into Noris' limited conclusion. D.I. 38 at 15. Samsung relies on the basic fact that "eculizumab was known to inhibit" C5, which is "downstream from the known complement defects in both PNH and aHUS responsible for hyperactivation." D.I. 38 at 15. Samsung's expert, Dr. Bissler, agrees however, that a POSA would know that eculizumab's effectiveness at treating any given disease involving hyperactivation of complement "would depend on more details about the disease." D.I. 49, Ex. A, 125:17-24. Without more than Noris's "hope," a POSA as of 2008 would have had no reasonable expectation that eculizumab would be effective to treat aHUS in any given individual patient. *See* D.I. 51 at ¶ 76.

Second, Samsung argues that the claim is anticipated by Chatelet (2008). While the Memorandum Order also finds that Chatelet (2008) "raises a substantial question of invalidity," the Memorandum Order "does not reach" any substantive analysis regarding 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." D.I. 57 at 5, 7 n. 2. Because the Court finds that Chatelet (2008) raises a substantial question without any substantive analysis, this finding did not support denial of Alexion's motion and would need to be addressed substantively on remand.

As Alexion outlined in its original briefing however, Chatelet (2008) is not even prior art and therefore could not be found by clear and convincing evidence to anticipate claim 1 of the '176 patent. *See* D.I. 49 at 6-8. Because the '803 Provisional discloses each and every limitation of claim 1, the '176 patent is entitled to a priority date of the '803 Provisional's filing date on November 10, 2008, which is the same date that Samsung alleges Chatelet (2008) was purportedly published.

[redacted]

[redacted]

For these reasons, Alexion is likely to succeed on appeal with respect to this Court's finding of a substantial question of validity as to the aHUS claim.

B. Absent an Injunction, Alexion Will Suffer Imminent and Irreparable Harm

Samsung's launch of SB12 will irreparably harm Alexion. "Price erosion, loss of good-will, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Research Found. of State Univ. of N.Y. v. Mylan Pharms., Inc.*, 723 F. Supp. 2d 638, 658 (D. Del. 2010). Availability of damages does not negate irreparable harm, given the market is inherently uncertain and not all harm is measurable. *See Hybritech v. Abbott Lab'ys*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988) ("[B]ecause the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole."); *Abbott*, 544 F.3d, 1361-62 ("loss of market opportunities cannot be quantified or adequately compensated").

1. Net Price Erosion Would Be Rapid and Irreversible

The direct competition between Alexion and Samsung will drive down the price of both companies' products, which will, in turn, lead to irreversible price erosion of Alexion's SOLIRIS® product. Price erosion constitutes irreparable harm because third-party payors for pharmaceutical products resist any attempts to return to pre-entry prices "once they experience paying a much lower price for [defendant]'s generic version of it." *Research Found.*, 723 F. Supp. 2d at 658.

[4] [redacted]

When a biosimilar enters the U.S. market, it is "typically priced at a 30% discount to the brand name biologic drug to which it is structurally similar." D.I. 18, ¶ 20 . Alexion estimates that a biosimilar introduction would result in price erosion of [redacted] *Id.*, ¶¶ 17, 30 . Alexion expects similar impact on the pricing and sales of its related drug, Ultomiris®, which is approved to treat PNH and aHUS. *Id.*, ¶ 20. Ultomiris' mechanism of action is similar to that of SOLIRIS®, but offers a more convenient dosing schedule and potentially other associated benefits for patients. *Id.*, ¶ 19. A premature launch of Samsung's SB12 biosimilar product will likely "erode Alexion's pricing power for Soliris and Ultomiris, which are the company's key drugs." *Id.*, ¶ 20.

Further, even if Samsung is forced to exit the market after a premature launch, Alexion will not have the ability to unilaterally restore the pre-Samsung launch price because market pricing will remain low. *Id.*, ¶¶ 15-17 . Thus, the expected price erosion supports a finding of irreparable harm. *See Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (irreparable harm of "irreversible price erosion in light of a complex pricing scheme that is directly affected by the presence of the generic product in the market," as "it is nearly impossible to restore [patentee's drug] to its pre-launch price").

2. Alexion Would Suffer Irreparable Losses in Market Share and Sales

In addition, a launch of Samsung's SB12 biosimilar product will inevitably cause Alexion to lose significant market share. "[D]irect competition between [the parties] . . . weighs in favor of finding irreparable harm." *Apple v. Samsung*, 809 F.3d 633, 641 (Fed. Cir. 2015). Biosimilar introduction generally leads "clinicians to reconsider their treatment choices as more options become available," and biosimilars designated as "interchangeable" can be "substituted for the reference product without the intervention of the healthcare provider." D.I. 18, ¶ 14. Also, the

Inflation Reduction Act (IRA) incentivizes physicians to use biosimilars by establishing an 8% add-on payment rate for biosimilars under Medicare Part B. *Id.* Alexion estimates that the entry of Samsung's biosimilar "would reduce Alexion's market share by [redacted] and erode the market share of SOLIRIS® [redacted] *See id.*, ¶¶ 15-16. Moreover, [redacted] resulting in further market fragmentation and loss of market share for Alexion. *See Abbott*, 544 F.3d at 1361 (affirming finding that generic manufacturer's sales would cause irreparable harm even though two other generic manufacturers were already on the market).

3. The Harm to Alexion's Reputation Is Unpredictable and Unquantifiable

Courts routinely find that reputational damage and loss of goodwill are instances of irreversible, unquantifiable harm warranting an injunction. *See, e.g.*, *Celsis*, 664 F.3d at 930; *Sanofi*, 470 F.3d at 1382-83; *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996). Alexion will suffer reputational harm if Samsung launches its infringing biosimilar. Alexion has a reputation as an innovator of safe and effective PNH and aHUS treatments and perpetually seeks to improve the standard of care, for example, by developing Ultomiris® and "educating prescribers on the benefits of Ultomiris as compared to SOLIRIS® due to the dosage regime and other potential associated benefits to such patients." D.I. 18, ¶ 34. The entrance of SB12 will "impact the rate at which patients may switch from Soliris to Ultomiris," and the differences between SB12 and SOLIRIS® may be difficult to communicate to the public, cause confusion among physicians and patients, and harm Alexion's reputation as the innovator of eculizumab. *See id.*; *Douglas Dynamics v. Buyer Prods.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013 (irreparable harm to patentee's "reputation as an innovator" if competitors were allowed to use the invention).

4. Causal Nexus Exists Between Samsung's Infringement and Irreparable Harm to Alexion

An injunction is proper because a causal nexus exists between Samsung's infringement and Alexion's irreparable harm—i.e., there is "some connection between the patented features and demand for the infringing product[]." *Apple*, 809 F.3d at 639, 641; *Genband US v. Metaswitch Networks*, 861 F.3d 1378, 1384 & n.2 (Fed. Cir. 2017) ("[C]ausal nexus and consumer demand may be apparent from the simple fact of infringing sales.").

The harm to Alexion ties directly to Samsung's infringement. Samsung could not launch its SB12 biosimilar but for infringement of Alexion's patents. Each of the irreparable harms discussed above will be a direct result of Samsung targeting hospitals and group purchasing organizations with a lower cost equivalent of SOLIRIS® that they would only use based on their association with Alexion's products. *See Mylan Inst., LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017) (causal nexus shown where defendant could not make its product without infringing the patents).

C. Samsung Will Not Be Substantially Injured and the Balance of Hardships Favors Alexion

The balance of hardships strongly favors Alexion. Without injunctive relief, Alexion will suffer the irreparable harms described above and lose the value of its hard-earned intellectual property reflecting decades of investment and innovation. Samsung, on the other hand, will suffer minimal harm from an injunction delaying the launch of SB12, because SB12 has not yet gained FDA approval. Samsung, therefore, does not currently derive revenue from sales of SB12. *See M/A-COM Tech. v. Laird*, 2014 WL 2727198, at *7 (D. Del. June 13, 2014) (balance of hardships favors patentee where defendant "presently derives no revenue from [accused product] sales"). The only potential harm to Samsung is the "time-shifting" of revenue, which carries little weight. *See Research Found.*, 723 F. Supp. 2d at 661 (citing *Glaxo Group Ltd. v. Apotex, Inc.*, 64 Fed.

App'x 751, 756 (Fed. Cir. 2003) (affirming injunction because "[patentee] would lose the value of its patent while [generic manufacturer] would only lose the ability to go on the market and begin earning profits earlier")); *LEGO v. ZURU*, 799 F. App'x 823, 832 (Fed. Cir. 2020) ("It is axiomatic that an infringer. . . cannot complain about the loss of ability to offer its infringing product.") For these reasons, the balance of hardships favors an injunction. *See Abbott*, 544 F.3d at 1362 ("preserving the status quo" because "[patentee] will lose much more if this Court did not enjoin [generic's] infringing conduct").

D. The Public Interest Favors Granting Interim Relief

The public interest favors an injunction. The public interest is best served by protecting investments in pharmaceutical research and development and enforcing valid patents. *See Pfaff v. Wells Elecs.*, 525 U.S. 55, 63 (1998); *Impax Lab'ys v. Aventis Pharm.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002). Protecting Alexion's patents will incentivize further innovation. *See Abbott*, 544 F.3d at 1362-63 ("significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents.") (internal quotation marks omitted). An injunction preserving the status quo will not harm the public, but rather, ensure continued patient access to safe and effective treatment. Alexion remains committed to providing SOLIRIS® to patients. Any public benefit Samsung attributes to selling its infringing product is outweighed by "the public interest in recognizing [Alexion's] patent rights, and more generally promoting continued, large-scale investment in research and development of new pharmaceuticals." *Research Found.*, 723 F. Supp. 2d at 663. Indeed, public policy does not support "eliminating the exclusionary rights conveyed by pharmaceutical patents" or "excuse infringement of valid pharmaceutical patents." *See Pfizer Inc. v. Teva Pharms.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). Thus, the public interest in allowing Alexion's case to be heard outweighs the temporary delay in availability of potentially cheaper drugs.

V. CONCLUSION

Alexion respectfully requests that the Court grant its motion for interim relief.

Dated: May 17, 2024

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on May 17, 2024 on the following counsel in the manner indicated below.

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