IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD.,	)	**REDACTED PUBLIC VERSION**
Plaintiffs,	)	C.A. 24-005-GBW
v.	)	
SAMSUNG BIOEPIS CO. LTD.,	)	
Defendant.	)	

SAMSUNG BIOEPIS CO. LTD.'S OPPOSITION TO PLAINTIFFS' EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL AND TEMPORARY RESTRAINING ORDER PENDING RESOLUTION OF THIS MOTION

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I. NATURE AND STAGE OF PROCEEDINGS

Alexion Pharmaceuticals, Inc. and Alexion Pharma International Operations Ltd. (collectively, "Alexion") filed this suit on January 3, 2024 (D.I. 1), and Samsung Bioepis ("Samsung") filed its Answer and Counterclaims on February 8, 2024 (D.I. 8). Alexion filed its Answer to Samsung's Counterclaims on March 14, 2024. D.I. 36. Separately, Alexion filed a Motion for a Preliminary Injunction ("PI Motion") on February 12, 2024. D.I. 16. Samsung opposed Alexion's PI Motion on March 15, 2024 (D.I. 38 ("Samsung's Opp. Br.")), and Alexion filed its Reply in Support of its PI Motion on April 11, 2024 (D.I. 49 (Alexion's Reply Brief ISO PI Motion)). The Court denied Alexion's PI Motion on May 6, 2024 (D.I. 57 ("PI Order")), finding a substantial question of validity with regard to claim 1 of U.S. Patent No. 10,590,189 ("the '189 patent") ("the PNH claim") and claim 1 of U.S. Patent No. 9,447,176 ("the '176 patent") ("the aHUS claim") (collectively, "PI claims"). Alexion filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit on May 14, 2024, and filed an Emergency Motion for Injunction Pending Appeal and Temporary Restraining Order Pending Resolution of This Motion ("Emergency Motion") on May 17, 2024.

II. SUMMARY OF ARGUMENT

Alexion has failed to meet its heavy burden to obtain the extraordinary relief of an injunction pending appeal. For the same reasons this Court denied Alexion's PI Motion, Alexion cannot establish the required "strong showing" that it is likely to succeed on the merits in its appeal. *Cipla Ltd. v. Amgen Inc.*, No. 19-44-LPS, 2019 WL 2053055, at *1 (D. Del. May 9, 2019). This Court properly concluded that Samsung established a substantial question of validity as to the PNH claim in view of the United States Patent Trial and Appeal Board's ("PTAB's") institution decision for *Inter Partes* Review ("IPR") of the '189 patent. This Court correctly reasoned that IPR estoppel does not prevent Samsung from relying on the PTAB's institution decision to establish a

substantial question of validity. For the aHUS claim, this Court also properly concluded that Samsung established a substantial question of validity based on obviousness in light of Noris (2005) and the SOLIRIS® label (2007), further strengthened by Samsung's argument based on anticipation by Chatelet (2008). Alexion offers the same substantive discussion of the validity of the aHUS claim that the Court previously considered and properly rejected. In addition, the testimony of Alexion's expert Dr. Josep Miquel Blasco Pelicano, whose deposition was taken after Alexion filed its Reply in Support of Its PI Motion, further undermines Alexion's arguments, and Samsung now incorporates that testimony into the record. Ex. A ("Blasco Dep. Tr.").

This Court properly found that Samsung established a substantial question of validity as to each of the PI claims, and thus held that Alexion failed to establish a likelihood of success on the merits of its claims. PI Order at 7. In so finding, this Court did not need to address the remaining factors considered as part of a motion for preliminary injunction. *Id.* at 2-3, 7. In any event, Alexion failed to make a clear showing of irreparable harm that is not compensable with money damages. Alexion's expert admitted that any alleged harms are quantifiable. Not only are they quantifiable, but Alexion has [redacted] Alexion also failed to provide the requisite nexus between the alleged harms and the asserted claims. Lastly, both the balance of hardships and public interest tip in favor of Samsung providing its SOLIRIS® (eculizumab) biosimilar product, SB12, to the market, given Alexion's well-laid plans anticipating biosimilar competition.

Finally, there is no emergency to justify Alexion's Emergency Motion; [redacted] Therefore, Alexion's request for

a temporary restraining order ("TRO") pending resolution of this Emergency Motion is unwarranted. Moreover, for all the reasons summarized above, Alexion is not entitled to a TRO. Alexion's Emergency Motion should be denied.

III. LEGAL STANDARD

To prevail on a motion for injunction pending appeal under Rule 62(d), Alexion must demonstrate "(1) a 'strong showing' that it is likely to succeed on the merits in its appeal; (2) absent an injunction it will be irreparably harmed; (3) an injunction or stay will not substantially injure [patentee]; and (4) an injunction will not harm the interests of the public." *Cipla*, 2019 WL 2053055, at *1 (denying Amgen's motion for injunction under Rule 62(d) despite finding irreparable harm and balance of hardship in favor of granting the injunction, because Amgen failed to establish likelihood of success on appeal); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762 (JAP), 2009 WL 1968900, at *2 (D.N.J. July 1, 2009) (a party seeking injunction pending appeal "bear[s] a very heavy burden of persuasion" (quoting *FTC v. Equitable Res., Inc.*, No. 07CV0490, 2007 WL 1500046 (W.D. Pa. May 21, 2007))); *see also Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. 19-149 (MN), 2019 WL 3855015, at *1 (D. Del. Mar. 5, 2019) (TRO "is governed by the same general standards that govern the issuance of a preliminary injunction" (quoting *Takeda Pharms. USA, Inc. v. West–Ward Pharm. Corp.*, No. 14-1268-SLR, 2014 WL 5088690, at *1 (D. Del. Oct. 9, 2014))).

At the preliminary injunction stage, if the alleged infringer presents an invalidity defense, "it is the patentee, the movant, 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). Such persuasion requires the patentee to establish that the invalidity arguments lack substantial merit. *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. 19-149-MN, 2019 WL 2521305, at

*4 (D. Del. June 6, 2019) (denying plaintiff's motion for a preliminary injunction when plaintiff failed to show that defendant's obviousness challenge lacked substantial merit). The alleged infringer need only raise a "substantial question" concerning validity, enforceability, or infringement of the asserted patents to defeat preliminary injunction. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997) (vacating the grant of a preliminary injunction when defendant raised a substantial question of validity of the asserted patent). The "substantial question" standard is "lower than what is required to prove invalidity at trial." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005–06, 1010 (Fed. Cir. 2009) (affirming the district court's denial of a preliminary injunction when defendants "made out a sufficient case of obviousness").

IV. ARGUMENT

Alexion has fallen far short of its heightened burden to make a "strong showing" of a likelihood of success on its appeal to obtain the drastic remedy of injunction pending appeal. Alexion essentially repeats the same arguments presented in its PI Motion. For the same reasons this Court denied the PI Motion, an injunction pending appeal should also be denied.

A. Alexion Has Not Provided a "Strong Showing" of Likelihood of Success on the Merits on Appeal

Alexion has not demonstrated a likelihood of success on the merits on appeal. "[T]o obtain reversal [of the denial of a preliminary injunction], the movant must show not only that one or more of the findings relied on by the district court was clearly erroneous, but also that denial of the injunction amounts to an abuse of the court's discretion upon reversal of erroneous findings." *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994) (affirming the district court's denial of preliminary injunction because there was no clear error in finding no irreparable harm). Alexion has failed to show an abuse of discretion, let alone any legal or factual error in the

Court's denial of the PI Motion. Therefore, Alexion failed to carry its burden to show a likelihood of success in reversing the Court's PI Order.

1. The Court Correctly Concluded That The '189 IPR Institution Decision Raises a Substantial Question of Validity of the PNH Claim

Neither of Alexion's two challenges to the Court's PI Order relating to the PNH claim is likely to succeed on appeal. First, Alexion argues that the Court attributed undue weight to the '189 PTAB institution decision, because institution decisions are preliminary and do not require a clear and convincing evidence burden of proof. D.I. 61 ("Op. Br.") at 4. Alexion's argument ignores the Court's well-reasoned PI Order and the law establishing the correctness of relying on IPR institution decisions to establish a substantial question of validity in the preliminary injunction context. *See* PI Order at 2-5. The Court's reliance on the PTAB institution decision is particularly justifiable here, where the PTAB: (1) provided a thorough, highly technical analysis of the arguments in a 67-page decision; (2) concluded that Samsung had demonstrated a reasonable likelihood of showing unpatentability at trial on three separate Grounds; and (3) identified specific errors made by the patent Examiner during prosecution of the '189 patent. *See* Samsung's Opp. Br. at 3-4, 9-12. The Court recognized the "extensive analysis of the validity of the PNH claim" by the PTAB and pointed out that "Alexion has not presented compelling evidence that the PTAB instituted that IPR in error . . . ." PI Order at 4. Contrary to Alexion's suggestion, the Court did not consider the PTAB's institution decision as "binding on the court" but instead assessed the PTAB's embrace of Samsung's arguments for invalidity and concluded that Alexion had not presented compelling evidence challenging the PTAB's analysis.[1]

[1] The cases Alexion cites are inapposite. *See* Op. Br. at 4. In *Tinnus Enterprises, LLC v. Telebrands Corp.*, the PTAB instituted post-grant review ("PGR") *after* the district court granted an injunction, and the Federal Circuit recognized that the parties could ask the district court to reconsider its preliminary injunction in light of the PTAB'S Decision. 846 F.3d 1190, 1201-02 (Fed. Cir. 2017). *Liqwd, Inc. v. L'Oreal USA, Inc.* relates to issues of trade secret misappropriation

The Court also properly recognized that Samsung is statistically very likely to prevail in its IPR. As the Court acknowledged, "[i]n FY2023, over 77% of instituted claims were cancelled in a final written decision." PI Order at 4 (citing D.I. 38, Ex. 10). Alexion does not dispute this statistic in its Emergency Motion.

Alexion's second challenge to the Court's PI Order is also likely to fail on appeal, because it improperly dismisses the equitable nature of the injunction remedy. Alexion argues that Samsung's invalidity defenses in its IPR "have no legal bearing on these preliminary injunction proceedings," because such arguments would not be available during a trial in district court. Op. Br. at 4-6. Alexion's audacious position is that it is entitled to the extraordinary remedy of preliminary injunction, ***even if it is likely that the PTAB will invalidate the '189 patent***. Alexion argues, without any legal support, that "[t]he IPR estoppel statute supersedes judge-made law regarding the equities at the preliminary injunction stage." *Id.* at 4. This Court recognized the illogical consequences of Alexion's argument, observing that "[t]his 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." PI Order at 4. Implicit in the Court's statement is that Alexion's argument compels a court to provide the extraordinary remedy of an injunction to a patent owner who likely has an invalid patent. Alexion asks the Court to ignore invalidity of the '189 patent, if the PTAB, rather than the district court, is likely to invalidate it. This is improper. Granting an injunction under these circumstances would contravene justice rather than deliver

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and breach of contract that the PTAB could not resolve and is not a preliminary injunction case. No. 17-14, 2018 WL 11189633, at *3 (D. Del. Dec. 12, 2018); *Genuine Enabling Tech., LLC v. Sony Corp.*, No. 17-135, 2020 WL 1140910, at *7 (D. Del. Mar. 9, 2020) relates to adopting the PTAB's claim construction and is not related to whether substantial questions of validity have been established.

justice, as equitable remedies are intended to do.

2. The Court Could Also Conclude That Samsung's Other Arguments Raise a Substantial Question of Validity and Enforceability Regarding the PNH Claim

Separate from the IPR institution decision, Samsung presented additional arguments challenging the PNH Claim, based on obviousness and inequitable conduct, in opposition to Alexion's PI Motion. Samsung's Opp. Br. at 9-13. These arguments raise substantial questions of validity and enforceability that may be decided independent of the PTAB's IPR institution decision. Should the Court revisit these arguments here, Samsung respectfully submits the Court will find further support for its prior finding that Alexion has not met its heavy burden to show likelihood of success on the merits of its PI claims.

3. The Court Correctly Found a Substantial Question of Validity Regarding the aHUS Claim

This Court correctly found that Samsung raised a substantial question of validity of claim 1 of the '176 patent ("the aHUS claim") based on obviousness, relying on the combination of Noris (2005) and the SOLIRIS® label (2007). PI Order at 5-7. While the Court did not reach Samsung's theory of anticipation by Chatelet (2008), it noted that "the existence of a second invalidity theory strengthens the Court's conclusion that there is a substantial question of validity." PI Order at 7 n.2. Alexion has raised no clear error or abuse of discretion by the Court. Nor does Alexion's Emergency Motion otherwise establish a "strong showing" of likelihood of success on appeal. The aHUS claim is both obvious and anticipated for all the reasons presented in Samsung's Response to Alexion's PI Motion and accompanying declaration of Dr. John Bissler. Samsung's Opp. Br.

at 13-19; D.I. 41 ("Bissler Decl."), ¶¶ 16-19, 75-128. In addition, testimony provided by Dr. Josep Miquel Blasco Pelicano ("Dr. Blasco") undercuts Alexion's arguments.[2]

a. The aHUS Claim Is Obvious in View of Noris (2005) and the SOLIRIS® Label (2007)

Alexion does not dispute that both Noris (2005) and the SOLIRIS® label (2007) are prior art to the '176 patent. Alexion also does not dispute that a POSA would have been motivated to combine Noris (2005) with the SOLIRIS® label (2007). Rather, Alexion's sole argument is that Noris (2005) merely expresses "hope," which Alexion asserts is not sufficient to establish a reasonable expectation of success. As the Court recognized, Alexion applies the wrong standard.

Applying the correct standard, the Court concluded 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." PI Order at 6. Dr. Blasco's opinions regarding a reasonable expectation of success should be disregarded because he applied the wrong standard. When asked during his deposition what would be required for a reasonable expectation of success, Dr. Blasco responded that a POSA would need clinical evidence of efficacy and safety of eculizumab in treating aHUS. Blasco Dep. Tr. at 109:3-14. Requiring such clinical evidence is the standard for anticipation, not the standard for a reasonable expectation of success. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (concluding that the district "clearly erred" in finding non-obviousness because the district court's reasoning would require "verifi[cation] through testing" to show reasonable expectation of success when "expectation of success need only be reasonable, not absolute"); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157,

[2] Alexion submitted new arguments regarding validity of the aHUS claim and a declaration from Dr. Blasco in its Reply Briefing, contradicting earlier representations. *See* Samsung's Opp. Br. at 13 n.6. Although the briefing and hearing schedule did not allow for a sur-reply brief, Dr. Blasco was deposed on April 29, 2024. Samsung provides excerpts from the transcript of that deposition in support of this brief.

1165 (Fed. Cir. 2006) (affirming the district court's finding of obviousness reasoning that "our case law makes clear that [reasonable expectation of success] does not require a *certainty* of success"). Moreover, Alexion's reliance in its brief on *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.* is misplaced because the information forming a reasonable expectation of success here is different and more extensive than in *Sanofi-Aventis.* No. 20-804-RGA, 2023 WL 4175334, at *13-14 (D. Del. June 26, 2023). In *Sanofi-Aventis*, prior art Phase I and II clinical studies suggested some treatment effect for the claimed investigational drug in an unclaimed cancer. *Id.* In contrast, eculizumab was no longer an investigational drug as of the priority date of the '176 patent. Rather, it was an FDA approved marketed drug indicated for the treatment of another complement hyperactivation disease, PNH (at an approved dosing regimen that is the same as the base claimed dosing regimen), and the mechanism by which eculizumab achieved its therapeutic effects was known. *See, e.g.*, D.I. 39, Ex. 7 ("Soliris label (2007)"); Samsung's Opp. Br. at 14; Bissler Decl., ¶¶ 48-56, 125-126; D.I. 51 ("Blasco Decl."), ¶¶ 49-51; Blasco Dep. Tr. at 146:17-147:1, 148:9-149:4. Additionally, well before 2008, and as acknowledged by Alexion and its expert, Dr. Blasco, a POSA recognized that both PNH and aHUS were hemolytic disorders caused by hyperactivation of the complement system, the complement system was well characterized, and the defects in complement responsible for aHUS were known. *See* Samsung's Opp. Br. at 14; Bissler Decl., ¶¶ 57-64, 108-111; D.I. 39, Ex. 3 ("Noris (2005)"). Thus, Noris (2005) and the SOLIRIS® label (2007) provide more than mere "hope" for expectation of success, as this Court concluded. PI Order at 6-7.

Alexion incorrectly argues that Samsung offers only attorney argument in support of a reasonable expectation of success. Alexion ignores Dr. Bissler's declaration testimony, which this Court properly relied on—testimony that in Dr. Bissler's opinion a POSA would have had a

reasonable expectation of success of applying the approved dosing regimen for eculizumab for PNH in the SOLIRIS® label (2007) to successfully treat aHUS. PI Order at 6. In his deposition, Dr. Bissler also confirmed that the Noris (2005) authors believed eculizumab would be effective in treating aHUS. *See* Ex. B (Bissler Dep. Tr.) at 81:10-22.

Alexion also misstates Dr. Bissler's opinion on reasonable expectation of success. His opinion is not, as Alexion contends, simply based on a reference to "hope" in Noris (2005). Instead, Dr. Bissler articulates the basis for a reasonable expectation of success as follows:

> In my opinion, one would first start with the FDA-approved dosing regimen of eculizumab for PNH, even to treat aHUS because the dosing regimen has already been found to be safe and effective in PNH patients and because of the similarities in the underlying cause of disease (complement system upstream hyperactivation and reduction of down-regulation). ***The fact that a POSA would have been aware that (1)*** eculizumab was known to block the pivotal cleavage step of C5 and the subsequent activation of the MAC complex of the complement system; ***(2)*** complement hyperactivation (or the reduction of down-regulation) was the underlying cause of the manifestation of both PNH and aHUS; ***(3)*** genetic mutations in complement components responsible for aHUS were upstream of eculizumab's site of action; ***(4)*** Noris (2005)'s express suggestion that eculizumab would be successful in treating aHUS; and ***(5)*** eculizumab was proven safe and effective for the treatment of PNH as of 2007 at the approved dosing regimen. ***This would have provided a POSA with a reasonable expectation of success that applying the approved dosing regimen for PNH would successfully treat aHUS***.

Bissler Decl., ¶ 126 (emphasis added).

Alexion ignores the extensive additional knowledge a POSA would have had beyond the expression of hope from Noris (2005). This knowledge included, for example, the mechanism of action that formed the basis for eculizumab's therapeutic effects and the fact that eculizumab acted downstream of known defects in the complement system that resulted in hyperactivation consequently in aHUS. Even Alexion's expert acknowledges these facts. *See* Blasco Dep. Tr. at 146:17-148:1, 152:20-153:4, 149:5-9; Blasco Decl., ¶¶ 49-50. Dr. Blasco also admits that a POSA would have had at least a suspicion that eculizumab would treat aHUS. Blasco Decl., ¶ 77; Blasco

Dep. Tr. at 103:18-104:14 (*see, e.g.*, "Q. Why would [a POSA] have made the hypothetical assumption that eculizumab could help treat aHUS in 2008? A. Eculizumab blocks the terminal phase of the complement . . . ."). Alexion has not established that the Court clearly erred in finding that a POSA would have had a reasonable expectation of success, and the combination of Noris (2005) and SOLIRIS® label (2007) raise a substantial question of obviousness of the aHUS claim.

b. The Court Should Revisit Samsung's Argument That Chatelet (2008) Presents a Substantial Question of Invalidity

As presented in Samsung's Response to Alexion's PI Motion and declaration of Dr. Bissler, the aHUS claim is also invalid because it is not entitled to a priority date before November 10, 2009, and Chatelet (2008) discloses every element of the claim. Samsung's Opp. Br. at 16-19; Bissler Decl., ¶¶ 65-67, 75-90, 96-105. While the Court did not reach this issue in its PI Order, Samsung respectfully submits this invalidity argument raises additional substantial questions of validity, particularly in view of the new sworn testimony of Alexion's expert, Dr. Blasco.

As explained in Samsung's responsive brief, claim 1 is not entitled to a priority date earlier than the PCT filing date of the '176 patent on November 10, 2009. Samsung's Opp. Br. at 16. None of the earlier priority applications supports the claimed maintenance dose of "at least 900 mg." *Id*. at 17. Alexion relies on its expert to argue that a POSA reading the "about 900 mg" in the '803 provisional (D.I. 39, Ex. 20) would understand the limitation to be interchangeable with the "at least 900 mg" claimed in the '176 patent. D.I. 49 (Alexion's Reply Brief ISO PI Motion) at 7; Blasco Decl., ¶¶ 57-58. But when Dr. Blasco was asked whether he believed "about" in the provisional to be the same as "at least" in the patent, he responded "I don't have an opinion in this regard because I did not write the documents." Blasco Dep. Tr. at 52:3-17. Moreover, Dr. Blasco's opinions regarding a POSA's understanding of the disclosures of the English language provisional and '176 patent should be given no weight because (1) Dr. Blasco is not a native English speaker;

(2) he communicates in either Spanish or Catalon at work and at home; (3) his deposition was conducted in Spanish; and (4) Dr. Blasco could only identify three paragraphs in his declaration that he had drafted, none of which were directed to the disclosure of the '803 provisional or the '176 patent. *Id.* at 13:1-14, 23:16-24:19. Therefore, Alexion cannot establish that the '176 patent is entitled to an earlier priority date than November 10, 2009, and Chatelet (2008) is prior art to the '176 patent.

Alexion does not dispute that Chatelet discloses every element of claim 1 of the '176 patent. And during his deposition Dr. Blasco confirmed that he never offers the opinion that Chatelet (2008) does not describe the method of treatment of claim 1. *Id.* at 58:2-9.

For the first time in its reply in support of its PI Motion, Alexion argued that [redacted]

[redacted] In fact, as confirmed by Dr. Blasco, Alexion's argument is pure speculation that should not be credited. [redacted]

Alexion bears the burden of proving that it invented claim 1 of the '176 patent before Chatelet (2008), and mere speculation and conjecture cannot meet that burden. *Kenexa Brassring, Inc. v. Taleo Corp.*, 751 F. Supp. 2d 735, 753 (D. Del. 2010) (finding that the patent did not enjoy an earlier priority date because plaintiff failed to establish prior invention by clear and convincing evidence). [redacted] Therefore, Alexion has not provided a "strong showing" that the aHUS claim is not invalid based on anticipation by Chalet (2008).

B. The Currently Scheduled Launch of SB12 Will Not Cause Alexion Any Imminent and Irreparable Harm

Although the Court did not need to reach the question of Irreparable Harm, Samsung reiterates its arguments here to emphasize that the Court's denial of the PI Motion is further justified by Alexion's failure to show irreparable harm if Samsung launches its biosimilar product, SB12. A party seeking a preliminary injunction must "make a 'clear showing' that it will suffer

irreparable harm and it is entitled to such relief." *Biogen Inc. v. Sandoz Inc.*, No. 22-1190-GBW, 2023 WL 7130655, at *2 (D. Del. June 29, 2023) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). The harm must be "immediate irreparable injury" that cannot be adequately compensated through monetary damages. *Biogen*, 2023 WL 7130655, at *2 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012)). Lastly, there must be a causal nexus between the alleged infringement and the alleged harm. *Biogen*, 2023 WL 7130655, at *2.

First, as a threshold matter, Alexion's composition of matter patents covering eculizumab began expiring in 2021 (D.I. 40, Ex. 35 (Alexion 2019 10-K) at 10), and its rush to settle Amgen's IPRs—and the PTAB's decisions to institute Samsung's IPRs—underscore that Alexion has no *valid* patent rights remaining that justify excluding Samsung's SB12 biosimilar from the market.

Second, Alexion's willingness to grant Amgen a royalty-free license to market its eculizumab biosimilar on March 1, 2025—two years before the expiration of the earliest-to-expire patents-in-suit—is completely inconsistent with its allegations of irreparable harm. The Amgen license *allows* the very same biosimilar competition that Alexion contends this Court should enjoin. D.I. 39, Ex. 9 (Amgen License), §§ 4(a)-(b) (granting Amgen a royalty-free license to commercialize Amgen Eculizumab Products beginning March 1, 2025); D.I. 18 (Thomas Decl.), ¶ 13 n.35 (noting patent expiration dates).

Third, and as explained in more detail below, Alexion's actions undermine its claims of irreparable harm for these additional reasons: (i) Alexion delayed filing its PI motion for seven months without any justification; (ii) Alexion [redacted]; and

(iii) Alexion's allegations of non-financial reputational harm from SB12's launch are speculative and unsupported by any evidence, and its allegations of harm to its workforce are refuted by the company's own documents.

Whether they are considered on a standalone basis or together, each of these reasons provides an ample basis to find that Alexion has not shown irreparable harm.

1. Alexion's Lengthy, Unexplained Delay in Filing Suit and Seeking a Preliminary Injunction Contradicts Its Allegations of Irreparable Harm

Alexion's seven-month delay in filing a PI motion weighs heavily against its claim of irreparable harm. *See Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("[E]vidence that a patent owner unduly delays in bringing suit against an alleged infringer negates the idea of irreparability."). Once Alexion received Samsung's notice of commercial marketing on July 7, 2023, notifying Alexion that it would not launch SB12 before the end of 180 days (January 3, 2024), it should have filed a PI motion as soon as possible, as contemplated by the BPCIA statute.[3] *See* 42 U.S.C. § 262(*l*)(8)(B) ("After receiving the [notice of commercial marketing] and *before such date of the first commercial marketing of such* biological product, the reference product sponsor may seek a preliminary injunction . . . ." (emphasis added)). The Federal Circuit has explained that the 180-day period triggered by the BPCIA's notice of commercial marketing "gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury." *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016) (holding that defendant is required to give notice of commercial marketing under § 262(*l*)(8)(A) to allow the patent owner 180 days to seek a preliminary injunction). Here, Alexion

[3] Notwithstanding Alexion's unexplained delay in presenting this Motion, [redacted]

delayed filing its complaint until the very last day of the 180-day period (D.I. 1 (filed Jan. 3, 2024)) and waited another month to file its PI motion. Alexion's lack of urgency in filing this motion, "particularly in light of relevant provisions under the BPCIA, should be sufficient by itself to deny the motion." *Genentech, Inc. v. Amgen Inc.*, No. 18-924-CFC, 2019 WL 3290167, at *3 (D. Del. July 18, 2019), *aff'd*, 796 F. App'x 726 (Fed. Cir. 2020) (denying defendant's motion for a preliminary injunction because plaintiff's delay in seeking a preliminary injunction disproved existence of irreparable harm).

2. Alleged Lost Sales and Price Erosion Will Be Quantifiable

Alexion's alleged lost sales and price erosion attributable to SB12 will be quantifiable (and therefore not irreparable) for two reasons: ***First***, Alexion's settlement and license agreement with Amgen [redacted] "The availability of adequate monetary damages belies a claim of irreparable injury." *Biogen*, 2023 WL 7130655, at *4 (quoting *Takeda*, 967 F.3d at 1349).

Second, the experts for both parties agree that the information necessary to calculate lost profit and price erosion damages with reasonable certainty would be available by the time of trial.

D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 25:2-12 (Alexion's damages expert Vincent Thomas admitting that "I would be able to calculate" Alexion's lost profits and price erosion damages by the time of trial); D.I. 42 ("Rao Decl."), ¶¶ 40-57 (explaining that damages could be calculated with reasonable certainty by the time of trial); *see* Rao Decl., ¶ 46 [redacted]

3. Alexion's Alleged Harms to Goodwill and Alleged Impacts from Workforce Redeployment Are Speculative

Alexion's assertion that its reputation as an innovator would be irreparably harmed by SB12's launch is contradicted by its willingness to license Amgen to sell its eculizumab biosimilar at least two years before the expiration of its eculizumab patents. *See* D.I. 18 (Thomas Decl.), ¶ 13 n.35 (noting patent expiration dates). Mr. Thomas, Alexion's expert, conceded that his opinions on harm to goodwill are not substantiated by any Alexion document or witness interview. D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 90:10-13 ("Q. Did you speak with any employee of Alexion concerning the potential impacts to reputation and goodwill that would manifest from a launch of SB12? A. I did not."). And Alexion's claim that SB12's launch would cause Alexion irreparable harm by preventing it from redeploying its workforce is unsupported by any evidence. D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 90:14-25 ("Q. Did you speak with any employee of Alexion regarding redeployment of Alexion's workforce that might be necessitated by the launch of SB12? A. I did not. Q. Did you look at any Alexion or third-party business advisor document that addresses whether Alexion will need to redeploy workforce as a result of Eculizumab biosimilar launching? A. There's no document that is based on the assumption of SB12 launching, so the documents

would not reflect that scenario. So I can't say that such documents exist."). [redacted] D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 102:18-22 ("Q. Okay. Have you seen any Alexion document that projects workforce reduction, as opposed to redeployment, as a result of biosimilar entry? A. As I said, that there are certain line items on this chart -- well, no, I don't."); *see also* Rao Decl., ¶¶ 58-60.

4. Alexion Failed to Carry Its Burden of Showing a Nexus Between Its Alleged Irreparable Harms and the PI Claims

Alexion has also failed to carry its burden of showing a nexus between its alleged harms and the alleged inventions in its PNH and aHUS claims. "Causal nexus requires some connection between the alleged infringement and harm such 'that the infringing feature drives consumer demand for the accused product.'" *Biogen*, 2023 WL 7130655, at *4 (quoting *Apple Inc.*, 695 F.3d at 1375). Harm cannot be presumed.

Internally, Alexion has identified branded competition—not biosimilars—as the primary threat to its SOLIRIS® and ULTOMIRIS® products. [redacted]

[4] Fabhalta® was FDA approved and launched in December 2023. *See* D.I. 40, Ex. 41.

[redacted] Alexion's motion ignores the reality that nearly all of the lost sales it forecast will be lost to branded drugs, not biosimilars. As a result of that oversight, Alexion failed to carry its burden of showing any nexus between its alleged irreparable harms and the alleged infringement of the patents asserted in its motion. D.I. 40, Ex. 36 (Thomas Dep. Tr.) 35:12-25 (admitting failure to parse out competitive impacts from branded competition). Alexion also failed to prove that the patents asserted in its motion are the basis of customer demand for SB12, versus its composition of matter patent covering the eculizumab, which began expiring in 2021 (D.I. 40, Ex. 35 at 10), or the other patents it owns. D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 84:16-86:13 (admitting failure to tie alleged harms to infringement of asserted patents); *see also* Rao Decl., ¶¶ 61-62; *see Biogen*, 2023 WL 7130655, at *4 ("Causal nexus requires some connection between the alleged infringement and harm such 'that the infringing feature drives consumer demand for the accused product.'").

C. The Balance of Equities Favors Denying Alexion's Motion

The balance of the equities and hardships tips strongly in Samsung's favor. Alexion's only alleged hardship is the "los[s] [of] the value of its hard-earned intellectual property reflecting decades of investment and innovation." Op. Br. at 12. But Alexion's key patents covering the composition of eculizumab began expiring in 2021. Rao Decl., ¶ 62 (citing D.I. 40, Ex. 35

[5] Alexion's arguments regarding irreparable harm to ULTOMIRIS® are speculative. [redacted] D.I. 40, Ex. 36 (Thomas Dep. Tr.) at 98:16-99:3, 100:1-23 (admitting ULTOMIRIS®' benefits.)

(Alexion 10K (2019)). And Alexion has already granted Amgen a royalty-free license to enter the market years before the expiration of these patents, which undermines its arguments about the balance of equities.

D. Denying Alexion's Preliminary Injunction Would Promote the Public Interest

Any injunction preventing Samsung from selling SB12 is against the public interest. Alexion's composition of matter patents began expiring in 2021. *Id.* The PI Claims cover using the antibodies for only two of the four FDA-approved uses. As this Court has recently recognized "[f]or pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs." *Biogen*, 2023 WL 7130655, at *10 (quoting *Genentech, Inc. v. Immunex Rhode Island Corp.*, 395 F. Supp. 3d 357, 366 (D. Del. 2019), *aff'd*, 964 F.3d 1109 (Fed. Cir. 2020)).[6] Samsung is committed to providing affordable biosimilars, such as SB12, to patients. The interest of a pharmaceutical company in maintaining its revenue and market share, on facts such as here, should not forestall access to FDA-approved, less expensive drugs for the public at large.

V. CONCLUSION

Based on the foregoing, Plaintiffs' motion for injunction pending appeal and temporary restraining order pending resolution of this motion should be denied.

[6] *Pfizer Inc. v. Teva Pharmaceuticals*, 429 F.3d 1364 (Fed. Cir. 2005) does not hold otherwise; rather, *Pfizer* stands for the proposition that, where the movant can show irreparable harm and a likelihood of success on the merits, a preliminary injunction may be appropriate in a pharmaceutical setting. That is not the case here.

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Dated: May 31, 2024

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of May, 2024, the attached **SAMSUNG BIOEPIS CO. LTD.'S OPPOSITION TO PLAINTIFFS' EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL AND TEMPORARY RESTRAINING ORDER PENDING RESOLUTION OF THIS MOTION** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ Andrew C. Mayo

Andrew C. Mayo

EXHIBIT A

REDACTED IN ITS ENTIRETY

EXHIBIT B

REDACTED IN ITS ENTIRETY