

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ACTELION PHARMACEUTICALS LTD.,)

Plaintiff,)

v.)

GLAND PHARMA LIMITED,)

Defendant.)

Civil Action No. 24-434-JLH-CJB

REDACTED VERSION

REPORT AND RECOMMENDATION

The Court, having reviewed Defendant Gland Pharma Limited's ("Defendant") motion for judgment on the pleadings ("Motion"), (D.I. 32), the briefing related thereto, (D.I. 33; D.I. 49; D.I. 58), and having considered the relevant legal standards, *see Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195-96 (3d Cir. 2019), hereby recommends that the Motion be DENIED for the following reasons.

1. With the Motion, Defendant argues that Plaintiff Actelion Pharmaceuticals Ltd. ("Plaintiff") is collaterally estopped from asserting United States Patent Number 8,598,227 ("the '227 patent"), the only patent-in-suit, in light of a court's non-infringement decision in another litigation involving Plaintiff and that same patent: *Actelion Pharm. Ltd. v. Mylan Pharm., Inc.*, No. 1:20-CV-110, D.I. 238 (N.D. W. Va. Mar. 15, 2024) ("the Mylan case"). (See D.I. 33 at 1) Though Defendant hasn't actually pleaded the affirmative defense of collateral estoppel in its Answer like it is supposed to, *see* (D.I. 49 at 6 (citing Fed. R. Civ. P. 8(c)(1))), because it provided Plaintiff with sufficient notice of its intent to raise this defense via the instant Motion, the Court will consider the merits of Defendant's argument herein, *see Kleinknecht v. Gettysburg Coll.*, 989 F.2d 1360, 1373-74 (3d Cir. 1993); (D.I. 58 at 2-3). The Court also hereby grants Defendant leave to amend its Answer in the future to add the defense. (D.I. 58 at 3)

2. The Court next notes that even had it found potential merit in Defendant's arguments regarding the Motion, the United States Court of Appeals for the Third Circuit has pretty strongly suggested that the right course then would *not* be to recommend grant of the Motion and dismissal of the case—but instead to consider other alternatives (e.g., denying the Motion without prejudice, or holding it in abeyance, or staying the case), in light of the fact that the Motion's merit is premised on the substance of a decision in the Mylan case that is currently on appeal and that could later be overturned. *See United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009) (*cited in* D.I. 49 at 13).

3. But that concern is academic here, as the Court does not see merit in the Motion.

4. Defendant's argument in support of the Motion is that: (a) All of the asserted claims require that an epoprostenol composition be formed from a bulk solution "having a pH of 13 or higher" or that is adjusted to be "greater than 13[.]" (D.I. 1, ex. A); (b) The court in the Mylan case ultimately construed "having a pH of 13 or higher" to mean "a pH of 12.98 or higher as measured [at standard temperature] $25\pm 2^{\circ}\text{C}$ [.]" (D.I. 34, ex. 3 at ¶ 112); (c) It was undisputed in the Mylan case that "[w]hen measured at $25\pm 2^{\circ}\text{C}$. . . Mylan's ANDA product does not meet the '13 or higher' limitation, [and so it] therefore d[id] not infringe." (*Id.* at ¶ 143); (d) Since "[t]here is no material dispute that the Gland and Mylan epoprostenol products *are the same* with respect to the critical non-infringing limitation [in that] both products are manufactured [REDACTED] [REDACTED] at standard temperature[.]"; then (e) this means that Plaintiff is collaterally estopped in this case from arguing that Defendant's product infringes, due to the result in the Mylan case. (D.I. 33 at 1-5, 8-11 (emphasis added))

5. However, it is Defendant's burden to demonstrate, *inter alia*, that the Mylan case involved the "same claim" regarding the literal infringement inquiry that is at play here—i.e.,

that the accused products in the two suits are essentially the same (or, put another way, that “the differences between them are merely colorable or unrelated to the limitations in the claim of the patent”). *Acceleration Bay LLC v. Activision Blizzard, Inc.*, 637 F. Supp. 3d 141, 145 (D. Del. 2022) (quoting *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1353 (Fed. Cir. 2017)). And the record here at the pleading stage does not clearly show that Defendant has met that burden. This is because, as Plaintiff argues: (a) The Mylan court’s claim construction facially requires consideration of a bulk solution’s pH throughout the temperature range of 23°C to 27°C—that is, 25 degrees plus or minus two degrees C.; (b) Defendant’s ANDA states that [REDACTED]

[REDACTED]

[REDACTED] (c) This means that it is plausible that Defendant’s [REDACTED]

[REDACTED] and (d) Since the record indicates that when temperature decreases, pH increases, this means it is also plausible that if measured at, for example, 23 degrees, the pH of Defendant’s [REDACTED] (D.I. 49 at 2, 6-11; *see also* D.I. 18, ex. 6 at ¶ 3.2.P.3.3.2; D.I. 34, ex. 3 at ¶ 17) The Court agrees with Plaintiff that, on this record—and giving it the benefit of all reasonable inferences—the above conclusions about Defendant’s product seem plausible; Defendant certainly has not clearly shown that they are *implausible*. Thus, the Court cannot conclude that the infringement issue here is “the same” as it was in Mylan—i.e., a case where it was undisputed that the bulk solution at issue did not meet the “13 or higher” limitation.

6. Because of the way the briefing shook out, Defendant’s comeback to Plaintiff’s argument was raised for the first time in its reply brief (so Plaintiff never really got the chance to respond to it). Therein, Defendant asserted that Plaintiff was simply “misinterpret[ing]” the Mylan court’s claim construction—and that the construction does *not* mean that the pH can be

measured at a range of temperatures (i.e., 25 degrees C, plus or minus 2 degrees C, or 23-27 degrees C)—but *instead* that the Mylan court’s construction requires that the pH be measured *only* at a “fixed temperature” of 25 degrees, full stop. (D.I. 58 at 1-7) But it is not clear, as a factual or legal matter, that Defendant’s reading of the Mylan court’s claim construction is correct. Indeed, the evidence before the Court suggests that Defendant’s reading is *not* correct. After all, the construction includes the wording “ ± 2 C[.]” (D.I. 34 at ¶ 143) That type of phraseology is typically understood to connote a range—in that it means “plus or minus two degrees.” If the Mylan court meant to hold that a “standard temperature” was simply 25 degrees (and nothing more or less), why wouldn’t it simply have said that? Defendant’s briefing never answers that question. And though there are times in the Mylan court’s decision on infringement and in Plaintiff’s appellate briefing where there are references to a standard temperature simply as being 25 degrees, (D.I. 58 at 4-5), there are also plenty of references in the Mylan court’s decision to the use of a “ ± 2 ” modifier—including references to this when the court is citing to the testimony of Plaintiff’s expert, (D.I. 34, ex. 3 at ¶¶ 22, 28, 54, 95, 97, 102, 111-12, 143). And so the Court cannot accept Defendant’s counter-argument here.

7. This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days from today’s date. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. Appx 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987). The parties are directed to the Court’s Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court’s website, located at <http://www.ded.uscourts.gov>.

8. Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **July 25, 2025** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the “kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.” *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: July 22, 2025


Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE