IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARMONY BIOSCIENCES, LLC, BIOPROJECT SOCIÉTÉ CIVILE DE RECHERCHE and BIOPROJECT PHARMA SAS, Plaintiffs, v. LUPIN LIMITED, *et al.*, Defendants.	REDACTED - PUBLIC VERSION Civil Action No. 23-1286-JLH [redacted]

MEMORANDUM ORDER

At Wilmington this **19th** day of **May, 2025**, the court having considered the parties' discovery dispute letter submissions (D.I. 308; D.I. 309), IT IS ORDERED that the pending joint motion for teleconference to resolve discovery disputes (D.I. 281) is addressed as follows:

1. **Background.** Plaintiffs filed this Hatch-Waxman case in November of 2023 against multiple defendants, alleging that those defendants submitted Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' Wakix® drug for the treatment of narcolepsy prior to the expiration of certain patents covering Wakix®. (D.I. 1) The active pharmaceutical ingredient ("API") in Wakix® is pitolisant hydrochloride. (*Id.* at ¶ 4) Two of the asserted patents, U.S. Patent Nos. 8,207,197 ("the '197 patent") and 8,345,430 ("the '430 patent"), cover a specific crystalline form of pitolisant hydrochloride. (D.I. 192, Ex. G)

2. Novitium, one of the seven companies seeking approval to manufacture and market a generic version of Wakix®, now moves for a protective order regarding the March 6, 2025 notice of deposition served on Muthsamy Shanmugam. As previously stated in the court's

Memorandum Order dated February 19, 2025, Shanmugam [redacted] authorized Novitium "to incorporate by reference information regarding [redacted] into any Application . . . filed by Novitium[.]" (D.I. 190, Ex. B) Subsequent correspondence between Shanmugam and the FDA confirms that Shanmugam was the FDA's point of contact for [redacted] Novitium's ANDA. (D.I. 190, Exs. J, K, M; D.I. 193, Ex. 1 at 6; D.I. 194 at ¶¶ 3-9)

3. Legal standard. "A party seeking a protective order bears the burden of showing good cause for its issuance." *Amicus Therapeutics US, LLC v. Teva Pharms. USA, Inc.*, C.A. No. 22-1461-CJB, 2023 WL 5289440, at *1 (D. Del. Aug. 17, 2023) (citing *Xerox Corp. v. Google, Inc.*, 270 F.R.D. 182, 183 (D. Del. 2010)); *see* Fed. R. Civ. P. 26(c). To establish good cause, the moving party must demonstrate with specificity "a particular need for protection and that absent the protective order . . . the movant will suffer a 'clearly defined and serious injury.'" *Signode Indus. Grp. LLC v. Polychem, LLC*, C.A. No. 22-519-VAC-CJB, 2022 WL 3226319, at *1 (D. Del. Aug. 10, 2022) (quoting *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 671 (3d Cir. 2019)); *see also AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, C.A. No. 17-1065-MSG, 2018 WL 2337133, at *1 (D. Del. May 23, 2018) (weighing "relevance, need, confidentiality and harm" in analyzing good cause).

4. Analysis. Novitium's motion for a protective order regarding the March 6, 2025 notice of deposition served on Muthusamy Shanmugam is DENIED without prejudice. The parties dispute whether a deposition of Muthusamy Shanmugam is proper under the apex doctrine, which generally bars the deposition of a high-ranking official when that official "does not have first-hand knowledge of relevant information, or if there are others equally well (or

better) situated to provide such information." *Brit. Telecommc'ns PLC v. IAC/Interactivecorp*, C.A. No. 18-366-WCB, 2020 WL 1043974, at *8 (D. Del. Mar. 4, 2020). Novitium contends that a protective order is appropriate under Federal Rule of Civil Procedure 26(b)(2)(C)(i) because Shanmugam's testimony would be cumulative of already-produced documents, the testimony of 30(b)(6) witness Chad Gassert, and fact witness testimony from Dr. Shivanand Puthli and Shek Sarafdeen. (D.I. 308 at 2-4) But Plaintiffs respond that Shanmugam has unique personal knowledge about the products at issue in the case, Novitium's ANDA, and [redacted] of the pitolisant hydrochloride supplied to Novitium. (D.I. 309 at 2)

5. The record before the court supports Plaintiffs' position that, as the point of contact for all FDA correspondence relating to Novitium's ANDA and the DMF, Shanmugam has relevant first-hand knowledge about the ANDA and the DMF, and he is uniquely situated to testify about [redacted] FDA correspondence, and Novitium's communications with the DMF holder. (D.I. 308, Ex. C at 43:6-18, 45:5-20; Ex. D at 1; D.I. 309, Exs. B-C; Ex. G at 125-28) The court previously determined that Shanmugam should not be restricted from testifying on issues relevant to this dispute. (D.I. 194 at ¶ 18) Although Novitium represented that its 30(b)(6) witness would be able to testify regarding ownership of the DMF, (D.I. 308, Ex. G at 1), the transcript from the 30(b)(6) deposition shows that the designee was unprepared to testify on the topic, (D.I. 309, Ex. G at 126-27, 202-03). Consequently, Shanmugam's testimony is not barred under the apex doctrine.

6. Novitium has not otherwise met its burden of showing good cause for the issuance of a protective order. Citing a stipulated agreement that Plaintiffs would forego "any foreign nonparty discovery from Nuray or any other nonparty," Novitium contends that Shanmugam

should not be required to testify about other Defendants' ANDAs. (D.I. 308 at 4) Specifically, Novitium argues that Shanmugam should not be required to testify about communications he exchanged regarding [redacted], which uses [redacted]. (*Id.*; D.I. 309 at 1) But Shanmugam is a U.S.-based witness and a U.S. employee of Novitium. Therefore, the parties' agreement not to pursue foreign nonparty discovery does not extend to Shanmugam's testimony on other Defendants' ANDAs. Plaintiffs have shown that this testimony is also relevant to the issues in the litigation because Shanmugam discussed [redacted] in communications regarding [redacted]. (D.I. 309 at 3) To the extent that other Defendants' ANDAs reference [redacted] Shanmugam has knowledge of communications regarding those ANDAs and DMFs, and the subject matter falls within the scope of the noticed deposition topics, Shanmugam's testimony should not be restricted only to Novitium's ANDA.

7. Novitium does not address any confidentiality issues regarding Shanmugam's testimony, it does not articulate a specific need for the requested protective order, and it presents no argument suggesting that it would suffer a clearly defined and serious injury in the absence of a protective order. Instead, Novitium focuses on the allegedly cumulative and duplicative nature of Shanmugam's anticipated testimony under the apex doctrine. Having determined that Shanmugam has noncumulative first-hand knowledge of relevant information, the court finds that a 30(b)(1) deposition of Shanmugam is appropriate under the circumstances of this case. *See Amicus Therapeutics*, 2023 WL 5289440, at *1.

8. Plaintiffs' deposition of Shanmugam should reasonably fall within the relevant areas of his unique knowledge. The deposition shall be limited in scope to the topics identified in

Plaintiffs' letter brief, *e.g.*, the pitolisant hydrochloride products at issue in this case, the preparation and submission of Novitium's ANDA and [redacted], the development of pitolisant hydrochloride [redacted], efforts to obtain approval of Novitium's ANDA product. (D.I. 309 at 2) Shanmugam may also testify regarding which entity is in possession of the FDA correspondence and which entity assumed ownership and all rights and responsibilities for [redacted] at any time during the relevant period, consistent with the court's February 19, 2025 Memorandum Order. (D.I. 194 at ¶ 18) Plaintiffs shall make reasonable efforts at Shanmugam's deposition to avoid duplicative or cumulative questioning on topics already addressed by Novitium's 30(b)(1) witnesses, Dr. Puthli and Mr. Sarafdeen, or its 30(b)(6) witness, Mr. Gassert.

9. Conclusion. For the foregoing reasons, IT IS ORDERED that Novitium's motion for a protective order is DENIED without prejudice. Shanmugam's deposition shall go forward on or before June 16, 2025. IT IS FURTHER ORDERED that the discovery dispute teleconference set for May 21, 2025 at 3:00 p.m. is CANCELLED.

10. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties shall jointly submit a proposed redacted version by no later than **May 26, 2025**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the

parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Memorandum Order issued.

11. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

12. 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 court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge