IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARMONY BIOSCIENCES, LLC, BIOPROJECT SOCIÉTÉ CIVILE DE RECHERCHE and BIOPROJECT PHARMA SAS,	)	
Plaintiffs,	)	Civil Action No. 23-1286-JLH
v.	)	**UNDER SEAL**
LUPIN LIMITED, *et al.*,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this **19th** day of **February, 2025**,

WHEREAS, plaintiffs Harmony Biosciences, LLC, Bioproject Société Civile de Recherche, and Bioproject Pharma SAS (collectively, "Plaintiffs) have moved to compel defendant Novitium Pharmaceuticals LLC ("Novitium"): (1) to produce documents concerning the relationship among Novitium, [redacted] as it relates to Novitium's ANDA products and/or pitolisant hydrochloride; and (2) to request all FDA correspondence regarding Drug Master File ("DMF") No. [redacted] from its DMF holder, [redacted] on an ongoing basis and to produce such correspondence, (D.I. 190); and

WHEREAS, Plaintiffs have moved to compel defendants Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited (together, "Zenara") to synthesize and produce a sample of a replacement batch of [redacted] pitolisant hydrochloride representative of the batch Zenara synthesized and destroyed in February of 2024, (D.I. 191); and

WHEREAS, the court has considered the parties' letter briefing, (D.I. 190; D.I. 191; D.I. 192; D.I. 193), IT IS ORDERED that Plaintiffs' Motions for Teleconference to Resolve Discovery Disputes are resolved as follows. (D.I. 185; D.I. 186)

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 and Zenara, two of the seven companies seeking approval to manufacture and market a generic version of Wakix®, are the subjects of Plaintiffs' pending discovery disputes. The facts pertinent to each are set forth below.

3. **Plaintiffs' motion to compel Novitium to request all FDA correspondence regarding Drug Master File ("DMF") No. [redacted] from [redacted] on an ongoing basis and to produce such correspondence is GRANTED-IN-PART.** In a letter of authorization dated June 6, 2023, [redacted] authorized Novitium "to incorporate by reference information regarding [redacted] into any Application . . . filed by Novitium[.]" (D.I. 190, Ex. B) The letter expressly identifies [redacted] as the DMF holder. (*Id.*) Accordingly, Novitium's ANDA No. 218495 references DMF No. [redacted], which outlines the processes used by the DMF holder to manufacture the pitolisant hydrochloride in Novitium's drug product.

4. Subsequent correspondence from the FDA dated [redacted] acknowledges [redacted] submissions made in [redacted]. (D.I. 190, Ex. J) This correspondence was addressed to [redacted], but it was sent to an email address with a [redacted] domain name. (*Id.*) The February 6 FDA letter identifies a deficiency in DMF No [redacted], which [redacted]. (*Id.*)

5. On [redacted], [redacted] responded to the FDA's DMF deficiency letter. (*Id.*, Ex. I) The responsive letter was sent on [redacted] letterhead, but the sender included a [redacted] email address. (*Id.*) The FDA replied on [redacted] in a letter addressed to [redacted] that lists the same [redacted] email address as the point of contact. (*Id.*, Ex. K) The FDA's [redacted] letter concludes that DMF No. [redacted] (*Id.*, Ex. K at 1)

6. Novitium produced its entire ANDA and the entire DMF on April 30, 2024. (D.I. 193, Ex. 3; D.I. 190, Ex. A at 8) Novitium also produced samples of its ANDA product and pitolisant hydrochloride [redacted], and it has agreed to produce correspondence with the DMF holder, [redacted] testing on its ANDA formulation, and FDA communications in its possession regarding either Novitium's ANDA or the DMF. (D.I. 193, Ex. 2 at 3-5) However, none of these productions included any communications by Novitium's DMF holder in response to the FDA's [redacted] letter.

7. On August 30, 2024, Plaintiffs served a subpoena on [redacted] seeking the production of DMF No. [redacted] and other documents and communications pertaining to pitolisant hydrochloride, including "[a]ll correspondence concerning DMF No. [redacted] between

you and the FDA, including but not limited to any deficiency letters, responses thereto, or other correspondence that postdates this subpoena." (D.I. 190, Ex. C at 7; D.I. 193, Ex. 4 at 8-9) [redacted] objected to each of the requests and declined to produce any responsive documents in its responses and objections served on October 4, 2024. (D.I. 190, Ex. C)

8. On October 16, 2024, Plaintiffs met and conferred with [redacted] about [redacted] responses and objections to the subpoena. (D.I. 193, Ex. 1 at 14) In subsequent correspondence between Plaintiffs and [redacted] on October 21, [redacted] held itself out as the holder of DMF No. [redacted] and confirmed that [redacted]. (*Id.*, Ex. 1 at 13) ("[W]e agreed during our meet and confer to consult with our client as to which parts of the two [redacted] DMFs have been turned over to certain Defendants in this case."). In correspondence exchanged on October 23 and November 11, 2024, [redacted] represented that it acts only as the regulatory agent for [redacted] with respect to another DMF, without making any representations about DMF No. [redacted]. (*Id.*, Ex. 1 at 8, 10)

9. On December 18, 2024, [redacted] acknowledged for the first time that it was not the holder of DMF No. [redacted] and it was "in the process of submitting documents to properly identify [redacted] as DMF holder." (*Id.*, Ex. 1 at 6) Four days later, [redacted] notified the FDA that it assumed ownership and became the holder of DMF No. [redacted] as of [redacted], and [redacted] served as the U.S. registered agent for [redacted] DMF. (D.I. 190, Ex. M) Accordingly, it would appear that [redacted] was the holder of DMF No. [redacted] until [redacted].

10. Plaintiffs seek an order compelling Novitium to request the FDA correspondence for DMF No. [redacted] from [redacted] and to produce any FDA correspondence received by Novitium in response to its request. (D.I. 190 at 4) According to Plaintiffs, this correspondence is relevant to

determine whether Novitium's proposed ANDA product uses the claimed crystalline form of pitolisant hydrochloride. (*Id.* at 3-4)

11. Novitium responds that Plaintiffs have not identified with specificity the additional FDA correspondence sought. (D.I. 193 at 1-2) This argument is unpersuasive. The record before the court establishes that the FDA sent letters addressed to [redacted] and Novitium in [redacted], respectively. (D.I. 190, Exs. H, K) These letters state that DMF No. [redacted], and they [redacted], as opposed to the [redacted] identified in the DMF. (*Id.*, Ex. K at 3-4) Novitium has not yet provided Plaintiffs with a response to this correspondence from [redacted], or Novitium.

12. The FDA correspondence Plaintiffs seek is relevant to the issues in the case. Any subsequent correspondence from Novitium or its DMF holder to the FDA is relevant to the structure, stability, and testing of the pitolisant hydrochloride at issue in this case. Specifically, the subsequent correspondence is likely to show whether Novitium's ANDA product uses the crystalline form of pitolisant hydrochloride claimed in the '197 and '430 patents. Without citation, Novitium represents that "[redacted]." (D.I. 193 at 2) (emphasis in original). Plaintiffs should be permitted to test this representation by reviewing the DMF holder's response to the FDA's [redacted] letter.

13. Novitium further contends that Plaintiffs' request is not proportional to the needs of the case and the documents it already produced are sufficient to evaluate infringement. (D.I. 193 at 3-4) But Plaintiffs anticipate that their request is not unduly burdensome and will likely yield a small quantity of documents. Novitium's ability to produce the FDA correspondence from

[redacted], as well as [redacted] letter to the FDA dated [redacted] suggests that Novitium can obtain the DMF holder's [redacted] without undue burden. (D.I. 190 at 4; Exs. I, J, K)

14. Novitium's position that Plaintiffs lacked diligence in seeking the requested discovery is unpersuasive. (D.I. 193 at 2-3) Plaintiffs had no reason to suspect that [redacted], and not [redacted] was the DMF holder until December 18, 2024. (D.I. 193, Ex. 1 at 6) Novitium and [redacted] consistently represented that [redacted] was the holder of DMF No. [redacted] until nearly four months after Plaintiffs subpoenaed [redacted] for the requested FDA correspondence. (D.I. 190, Ex. C; D.I. 193, Ex. 1)

15. Novitium argues that "Plaintiffs have or should have known since at least October 23, 2024, if not earlier, that [redacted] is the DMF holder." (D.I. 193 at 2) In the same paragraph, Novitium states "when [redacted] learned that it was erroneously listed as owner of [redacted] DMF, it notified Plaintiffs within days—even before a correction was submitted to FDA." (*Id.*) The corresponding citation refers to the December 18, 2024 email. (*Id.*, Ex. 1 at 6) It is inconsistent to argue that Plaintiffs should have known the correct identity of the DMF holder on October 23, when [redacted] allegedly did not discover the error until December 18. Novitium does not explain how [redacted] failed to recognize it was listed as the DMF holder even though the FDA addressed all correspondence regarding DMF No. [redacted]. And it is unclear how Plaintiffs could "know" since October 23 that Nuray was the DMF holder when [redacted] letter to the FDA states that it only assumed ownership of DMF No. [redacted] "as of [redacted]." (D.I. 190, Ex. M)

16. Although Novitium correctly observes that the court cannot force a third party to comply with discovery demands through an order issued to a party in the case, the record before

the court shows that a request by Novitium is likely to be sufficient to obtain the discovery. Therefore, IT IS ORDERED that, on or before **March 6, 2025**, Novitium shall: (a) request all FDA correspondence regarding DMF No [redacted] from the DMF holder, [redacted] on an ongoing basis and produce to Plaintiffs any FDA correspondence received in response to Novitium's requests to [redacted]; or, alternatively, (b) verify, in a declaration under oath, that in the event that Novitium is notified by [redacted] of any change to the drug substance used in Novitium's ANDA products, it will produce documents and samples in its possession relating to any such change in accordance with its obligations under Rule 26(e) and, as of the date of the declaration, it has not been so notified. To avoid further delays caused by the lack of clarity of the DMF holder's identity and other obstacles to discovery, Plaintiffs may also simultaneously pursue relief under the Hague Convention on or before **March 6, 2025**. Although the Hague process may not be complete by the close of fact discovery on April 18, 2025, there is sufficient time in the schedule to initiate such discovery in this ANDA case where case dispositive motions are not permitted and the bench trial will begin on February 17, 2026. (D.I. 34)

17. Plaintiffs' motion to compel Novitium to produce documents regarding the relationship among various entities as it relates to Novitium's ANDA products and/or pitolisant hydrochloride is GRANTED-IN-PART. Plaintiffs represent that Novitium agreed to produce its contract(s) with its DMF holder, but it has not yet done so. (D.I. 190, Ex. 2) Novitium's responsive letter does not address the status of the production. (D.I. 193) Accordingly, Plaintiffs' motion is GRANTED with respect to Novitium's production of its contract(s) with its DMF holder, which shall be completed on or before **March 6, 2025**.

18. Plaintiffs' request for discovery on the relationship among [redacted], and Novitium is otherwise DENIED as overbroad and only tangentially relevant to the matter of

which entity is in possession of the FDA correspondence discussed *supra*. However, in the event that [redacted] is deposed, this ruling is not intended to limit Plaintiffs from examining [redacted] during the deposition about which entity assumed ownership and all rights and responsibilities for DMF No. [redacted] at any time during the relevant period, consistent with the chronology set forth above.

19. Plaintiffs' motion to compel Zenara to synthesize and produce a sample of a replacement batch of [redacted] pitolisant hydrochloride representative of the batch Zenara synthesized and destroyed in February of 2024 is DENIED without prejudice. Defendant Zenara's ANDA No. 218796 references DMF No. 037753, which covers the pitolisant hydrochloride [redacted] in Zenara's generic 4.45 mg and 17.8mg pitolisant tablets. Pitolisant hydrochloride [redacted] pitolisant hydrochloride [redacted] (D.I. 192, Ex. A at Pitoli_0027173)

20. On February 5, 2024, the FDA requested the manufacture and testing of [redacted] pitolisant hydrochloride to obtain characterization data on the [redacted] pitolisant hydrochloride, as opposed to pitolisant hydrochloride [redacted], which is a [redacted] (D.I. 191, Ex. A) In response to the request, Zenara manufactured a limited batch of [redacted] pitolisant hydrochloride by removing a portion of the aqueous solution of pitolisant hydrochloride [redacted] and freeze drying the aqueous solution. (*Id.*, Ex. E; D.I. 192, Ex. C) This yielded 10.6 grams of [redacted] pitolisant hydrochloride. Six grams were consumed in testing, and the remaining 4.6 grams were discarded in late February of 2024. (D.I. 192, Ex. H at ¶¶ 14-16)

21. In discovery requests served on July 26, 2024, Plaintiffs asked Zenara to produce at least 50 grams of the characterization samples of [redacted] pitolisant hydrochloride it prepared in

response to the FDA's DMF request. (D.I. 191, Ex. D at 9) Zenara objected to producing the characterization samples because it had none left. Instead, it produced: (i) all characterization data that was provided to the FDA; (ii) sample tablets from each exhibit batch of each dosage strength of the ANDA products; (iii) 25 grams of representative bulk pitolisant hydrochloride [redacted] from two lots; and (iv) samples of the [redacted] used to create the pitolisant hydrochloride [redacted]. (D.I. 191, Ex. C at 1; D.I. 192, Exs. F, H)

22. Plaintiffs contend that Zenara should be compelled to manufacture and produce a replacement batch of [redacted] pitolisant hydrochloride representative of the batch Zenara destroyed in February of 2024. (D.I. 191 at 2) According to Plaintiffs, these samples are relevant to determining whether the [redacted] pitolisant hydrochloride in Zenara's ANDA products meets the crystalline form limitations in the asserted patents for purposes of infringement. (*Id.* at 2-3) Plaintiffs maintain that the samples produced to date are insufficient because "[i]t is significantly more difficult to assess an analysis of a mixture for the presence of the particular 'signature' of pitolisant hydrochlorides as compared to assessing the analysis of [redacted] pitolisant hydrochloride." (*Id.* at 3) Plaintiffs represent that samples of the [redacted] pitolisant hydrochloride "may assist in identifying the particular identifying characteristics of the pitolisant hydrochloride in Zenara's ANDA products." (*Id.* at 2)

23. Zenara responds that samples from a replacement batch would not be relevant to Plaintiffs' infringement claims because [redacted] pitolisant hydrochloride is not a component of Zenara's manufacturing process of the pitolisant hydrochloride [redacted] and it is, therefore, not representative of Zenara's ANDA products. (D.I. 192 at 2-3) Moreover, Zenara emphasizes that Plaintiffs' infringement contentions are centered on the theory that Zenara's ANDA products, after manufacture and upon storage, contain crystalline pitolisant

hydrochloride, and samples of [redacted] pitolisant hydrochloride lack relevance to what is alleged to infringe. (*Id.* at 2 & n.3; Ex. G) Even if the requested samples are of limited relevance, Zenara contends that it should not be compelled to produce them because the samples are not within Zenara's possession, custody, or control, and the burden of manufacturing and producing the requested samples outweighs their probative value. (*Id.* at 3-4) Zenara alleges that the information Plaintiffs seek can be obtained from other, less burdensome sources, such as the samples already produced and the characterization data on the [redacted] pitolisant hydrochloride that was provided to the FDA. (*Id.* at 4) According to Zenara, "XRD testing[1] of the produced samples of the pitolisant hydrochloride [redacted] and the [redacted] sample would enable Plaintiffs to identify any diffractogram peaks corresponding to the pitolisant hydrochloride by subtracting peaks obtained from the [redacted] sample." (*Id.*)

24. Samples of the [redacted] pitolisant hydrochloride are of some relevance to the infringement inquiry because they can be used to determine whether the [redacted] pitolisant hydrochloride satisfies the limitations of the crystalline form claims in the '197 and '430 patents. As Plaintiffs explain, the production of API samples in ANDA litigation is common. *See Astellas US LLC v. Apotex, Inc.*, C.A. No. 18-1675-CFC-CJB, D.I. 247 at 2 (D. Del. Apr. 30, 2020). However, the relevance of the API samples may be lessened if those samples do not represent the material actually used to create the ANDA product. *Id.*; *see also Merck Sharp & Dohme Corp. v. Amneal Pharms. LLC*, 881 F.3d 1376, 1385 (Fed. Cir. 2018) ("Regardless of the type of sample (e.g., commercial or batch), the critical inquiry is whether it is representative of what is likely to be approved and marketed."). Here, Zenara contends that "[a]t no point during this DMF manufacturing process is the pitolisant hydrochloride [redacted]." (D.I. 192 at 1; Ex. H

[1] "XRD" testing means "x-ray diffraction" testing.

at ¶¶ 18, 23) This appears to be an undisputed point for purposes of this discovery dispute because Plaintiffs do not argue otherwise.

25. Even if the court were to determine that the [redacted] pitolisant hydrochloride samples are highly relevant to the infringement analysis, the burden of producing them outweighs their relevance on this record. There is no dispute that Zenara does not have samples of the [redacted] pitolisant hydrochloride in its possession, and it would need to engage in a special manufacturing process to create samples because it does not [redacted] pitolisant hydrochloride as part of its manufacturing process. (D.I. 192, Ex. H at ¶¶ 18-20) Preparing the requested samples would involve acquiring the key materials for manufacture from external sources and "divert[ing] chemists' efforts from other ongoing projects[.]" (*Id.*, Ex. H at ¶ 20)

26. Moreover, less burdensome means of obtaining the information are available. Zenara produced samples of its ANDA products, the pitolisant hydrochloride [redacted] and the [redacted] used to create the pitolisant hydrochloride [redacted] Zenara represents that "XRD testing of the produced samples of the pitolisant hydrochloride [redacted] and the [redacted] sample would enable Plaintiffs to identify any diffractogram peaks corresponding to the pitolisant hydrochloride by subtracting peaks obtained from the [redacted] sample." (D.I. 192 at 4) Plaintiffs do not address this scenario and instead focus only on the pitolisant hydrochloride [redacted] sample, noting that "[i]t is significantly more difficult"—but presumably not impossible—to identify the signature for [redacted] pitolisant hydrochloride when it is [redacted]. (D.I. 191 at 3)

27. The authority cited by Plaintiffs further supports a conclusion that the samples already produced by Zenara are sufficient to identify the diffractogram peaks of [redacted] pitolisant hydrochloride through XRD testing. In *Bristol-Myers Squibb Co. v. Aurobindo*

Pharma USA Inc., the court held that the ANDA product contained crystalline particles of the API based on XRD testing of the entire ANDA product, as opposed to the isolated API. 477 F. Supp. 3d 306, 347 (D. Del. 2020). Plaintiffs have not provided an expert declaration or other evidence to suggest that it is not possible to identify the diffractogram peaks of [redacted] pitolisant hydrochloride from XRD testing of the ANDA product, the pitolisant hydrochloride [redacted] sample, and / or the [redacted] sample.[2] Plaintiffs' position that samples of [redacted] pitolisant hydrochloride "may assist" in identifying the characteristics of the [redacted] pitolisant hydrochloride and relying on the samples already provided would make it "significantly more difficult" to do so indicates that the same result can be achieved with the samples provided. (D.I. 191 at 2-3) On this fact specific record, the court holds that compelling the manufacture and production of [redacted] pitolisant hydrochloride samples is burdensome and disproportional to the needs of the case.

28. Conclusion. For the foregoing reasons, IT IS ORDERED that:

A. Plaintiffs' motion to compel Novitium to request all FDA correspondence regarding DMF No. [redacted] from [redacted] on an ongoing basis and to produce such correspondence is GRANTED-IN-PART. On or before **March 6, 2025**, Novitium shall: (a) request all FDA correspondence regarding DMF No. [redacted] from its DMF holder, [redacted] on an ongoing basis and produce to Plaintiffs any FDA correspondence received in response to Novitium's requests to [redacted] or, alternatively, (b) verify, in a declaration under oath, that in the event that

[2] The court concludes that oral argument would not be helpful in this instance because neither party submitted an expert declaration addressing whether XRD testing on the samples provided can reveal the data sought on the [redacted] pitolisant hydrochloride, or whether testing on the [redacted] pitolisant hydrochloride is absolutely necessary to determine whether the crystalline form limitation in the asserted claims is met by Zenara's ANDA product.

Novitium is notified by [redacted] of any change to the drug substance used in Novitium's ANDA products, it will produce documents and samples in its possession relating to any such change in accordance with its obligations under Rule 26(e) and, as of the date of the declaration, it has not been so notified. Plaintiffs may also simultaneously pursue relief under the Hague Convention on or before **March 6, 2025**.

B. Plaintiffs' motion to compel Novitium to produce documents regarding the relationship among various entities as it relates to Novitium's ANDA products and/or pitolisant hydrochloride is GRANTED-IN-PART. Plaintiffs' motion is GRANTED with respect to Novitium's production of its contract(s) with its DMF holder, which shall be completed on or before **March 6, 2025**. Plaintiffs' request for discovery on the relationship among [redacted], and Novitium is otherwise DENIED without prejudice. If [redacted] is deposed, this ruling is not intended to limit Plaintiffs from examining [redacted] during the deposition about which entity assumed ownership and all rights and responsibilities for DMF No. [redacted] at any time during the relevant period.

C. Plaintiffs' motion to compel Zenara to synthesize and produce a sample of a replacement batch of [redacted] pitolisant hydrochloride representative of the batch Zenara synthesized and destroyed in February of 2024 is DENIED without prejudice.

IT IS FURTHER ORDERED that the discovery dispute teleconference set for February 20, 2025 at 2:00 p.m. is CANCELLED.

29. 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 **February 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.

30. 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.

31. 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