IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., and GILEAD SCIENCES, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 18-1675-CFC-CJB
APOTEX INC., et al.,	)	
Defendants.	)	

MEMORANDUM ORDER

Defendants Apotex Inc., Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories, Inc., Hospira, Inc., and International Medication Systems, Ltd. ("Defendants") have moved for relief against Plaintiffs Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. ("Plaintiffs") regarding this discovery dispute ("Motion"). (D.I. 517) The Court[1] has considered the parties' letter briefs, (D.I. 507; D.I. 519), heard argument on October 26, 2020 and considered the parties' supplemental briefing related thereto, (D.I. 537; D.I. 538).

Defendants each request that Plaintiffs produce a representative physical sample of the Lexiscan active pharmaceutical ingredient ("API" or "Lexiscan API"). (D.I. 507 at 1) Defendants argue that the sample is relevant, primarily because: (1) in this case, Plaintiffs are arguing that the asserted patents are valid, and in doing so, are asserting that various objective indicia of non-obviousness relating to their product (that contains the Lexiscan API, hereinafter the "Lexiscan Product") help to demonstrate validity; (2) yet Defendants will argue that the Lexiscan Product does not embody the asserted claims, in that the claims require a

[1] This case has been referred to the Court to resolve all disputes relating to discovery and the protective order. (D.I. 186)

"monohydrate" that is a "crystal structure[,]" and the Lexiscan Product does not contain the claimed crystal structure; (3) thus, Defendants will argue that there is no "nexus" between any relevant objective indicia evidence and the asserted claims. (D.I. 507 at 1-3); *see also Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019). In response, Plaintiffs argued, *inter alia*, that: (1) only some, not all, asserted claims require a crystal structure—i.e., only those claims to a monohydrate that is "crystalline"; and (2) in any event, there is no doubt that the Lexiscan Product is made from "crystalline regadenoson monohydrate" (and that, for example, one can tell that from XRPD data that is already available to Defendants), and so there is no need to give Defendants the opportunity to further challenge that point by getting access to the Lexiscan Product. (D.I. 519 at 1-3)[2]

It appears to the Court very clear that, pursuant to the District Court's claim construction, at least some of the asserted claims require a "crystalline" monohydrate, and that this means a monohydrate with a "crystal structure." (D.I. 537, ex. 30 at 21-24) So if Defendant could show that the Lexiscan Product does not have a "crystal structure," that would seem to at least be relevant to whether any such claims could have a nexus to any relevant objective indicia. And the Court disagrees with Plaintiffs that producing the API samples is not necessary because Plaintiffs have produced other analyses purporting to support the crystalline nature of the API. Defendants should be permitted access to relevant discovery in order to attempt to challenge that

[2] Plaintiffs also argue that Defendants are really asserting that the claims require not just a crystal structure, but a "*resolved single-crystal structure*[.]" (D.I. 538 at 2 (emphasis in original)) It is not clear to the Court, however, that Defendants are really making that argument. (D.I. 537 at 2 ("Defendants respectfully submit that Plaintiffs are obligated to produce physical samples to allow Defendants to conduct the same types of studies that Plaintiffs directed to attempt to determine whether Lexiscan[] API material, in fact, *contains a monohydrate crystal structure*.") (emphasis added))

conclusion, i.e., to determine, *inter alia*, the extent to which the API does or does not conform to the "crystalline" limitation set out in the claims. (D.I. 537 at 2)

Therefore, for the reasons set out below, the Court hereby ORDERS that the Motion is GRANTED. The parties shall further meet and confer on the appropriate timing of any production.

Because this Memorandum Order 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 document. Any such redacted version shall be submitted by no later than **November 9, 2020** for review by the Court, along with a motion for redaction 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." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: November 4, 2020

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE