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.,	)	(CONSOLIDATED)
Defendants.	)	

MEMORANDUM ORDER

At Wilmington, Delaware this **13th day of April, 2020**.

WHEREAS, Plaintiffs Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. ("Plaintiffs") have moved for relief against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("DRL" or "Defendants") to compel them to produce "(1) samples of the active pharmaceutical ingredient ('API') used to make DRL's ANDA Product; and (2) documents and communications concerning agreements between DRL and [additional Defendants] Sandoz and/or Apotex relevant to this case[,]" (D.I. 219 at 1), and;

WHEREAS, Defendants have also moved for relief against Plaintiffs to compel them to produce Lexiscan® API, "Form A" of regadenoson monohydrate, and the amorphous and liquid forms of the regadenoson monohydrate, (D.I. 218 at 2); and the Court[1] has considered the parties' letter briefs, (D.I. 218; D.I. 219; D.I. 223; D.I. 224), and heard argument on April 6, 2020 (D.I. 230, hereinafter "Tr."),

[1] The Court has been referred for resolution all disputes relating to discovery and the protective order. (D.I. 186) In accordance with the Court's discovery dispute procedures, the parties filed a joint motion seeking resolution of the instant discovery disputes, (D.I. 217).

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. As to Plaintiffs' request for samples of the API used to create Defendants' ANDA Product, the Court notes that in this litigation, Plaintiffs' patents require the utilization of regadenoson *monohydrate*. (D.I. 223 at 1; *see also* D.I. 219 at 1) Defendants have taken the noninfringement position that their ANDA Product contains [redacted]. (*See* D.I. 223 at 1) So, to prove up their case, Plaintiffs seek to obtain samples of the API used to create Defendants' ANDA Product and test them to determine whether, in fact, Defendants' proposed drug product will satisfy these claim limitations. In situations like this, the ANDA Product (and by extension, the API) is relevant evidence when "the ANDA specification . . . [does] not define the compound in a manner that directly addresse[s] the issue of infringement." *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000); *see also BioDelivery Scis. Int'l, Inc. v. Chemo Research S.L.*, Civil Action No. 19-444-CFC-CJB, D.I. 72 at 2-3 (D. Del. Nov. 8, 2019) (citing cases).

2. Plaintiffs contend that Defendants' ANDA is unclear as to whether Defendants' product meets these particular claim limitations. (D.I. 219 at 2; *id.*, ex. I at EUT(REG)_00001037) Defendants, for their part, do not seem to dispute this. (D.I. 223) Instead, the parties' dispute concerns *which* API sample Defendants should produce. Defendants offer a sample of the API material that they recently purchased, which was created in May 2019 and is located in Missouri. (D.I. 223 at 1-2) This is not acceptable to Plaintiffs, who instead demand that Defendants produce an API sample from a batch located in India that was created in September 2016. (D.I. 223, ex. 11 at DRL(REG)_00000772, DRL(REG)_00000776) Plaintiffs make this demand because the API material in India is from the same batch as the API that was actually used to create the ANDA Product. (D.I. 223 at 1-2; Tr. at 33) This would thus seem to

make the material from India more "representative" of the product Defendants actually intend to market than the material from Missouri. (*See* D.I. 219 at 1 n.2; Tr. at 42-43) Furthermore, there seems to be good indication that this API material from India is not expired, (*see, e.g.*, D.I. 223, ex. 14; *see also* Tr. at 40-41), and even if it was expired, it would still be relevant to the infringement dispute at issue, *see BioDelivery Sciences*, Civil Action No. 19-444-CFC-CJB, D.I. 72 at 3. The Court therefore GRANTS Plaintiffs' request. The parties shall further meet and confer to discuss issues related to the timing of such production.

3. As to Plaintiffs' request for documents and communications concerning agreements between DRL and the other defendants in this case, the Court DENIES this request AS MOOT. During oral argument, Defendants' counsel: (a) confirmed that there were no such agreements; and (b) offered that Defendants would supplement their response to the relevant Requests for Production to answer the full scope of the requests and make clear that there were no such responsive documents. (Tr. at 34-35) The Court further ORDERS Defendants to do so by **April 17, 2020**. In light of this, there is no need to order the relief sought by Plaintiffs.

4. As to Defendants' (somewhat more unusual) request for samples of Lexiscan API and of "Form A" of the regadenoson monohydrate, (D.I. 218 at 1-2), the Court understands Defendants' position to be that these samples are primarily relevant to Plaintiffs' reliance on certain objective indicia of nonobviousness, (*id.* at 2; D.I. 224 at 2) The Court also understands that Lexiscan API and "Form A" refer to the same substance. (Tr. at 60). Plaintiffs argue that it is beyond doubt that its Orange Book-listed patents cover Lexiscan, and so any discovery on this point (i.e., discovery as to whether there is a nexus between the claimed drug product and certain objective indicia, in light of a possible argument by Defendants that Lexiscan does not actually contain the required monohydrate) would be wasteful. In support of this argument, Plaintiffs

point to their representations to the FDA—sworn under penalty of perjury—that Lexiscan is covered by United States Patent Nos. 8,106,183 (the "'183 patent") and RE47,301 (the "'301 patent" and collectively, the "patents-in-suit"). (D.I. 224, ex. Q at AST-LEX_0047970; *id*., ex. R at AST-LEX_00053060) And in their briefing and during oral argument, Defendants did not explain clearly enough to the Court why this point was even possibly in dispute, or how the record demonstrates that there is some question that this is so, sufficient to articulate why Defendants need to obtain the samples in discovery. (D.I. 218 at 2; Tr. at 64-65) Therefore, the Court DENIES WITHOUT PREJUDICE this request. If Defendants can better articulate some basis in evidence for their doubt, they may later renew this request.

5. Last, as to Defendants' request for the "amorphous" and "liquid" forms of regadenoson monohydrate, Plaintiffs' counsel represented at oral argument that Plaintiffs have no such samples in their possession. (Tr. at 61) The Court therefore DENIES this request AS MOOT. The Court further ORDERS Plaintiffs to supplement any relevant discovery response(s) to match this representation by no later than **April 17, 2020**.

6. 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 **April 17, 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.

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE