IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM ORDER

Defendants Apotex Inc. ("Apotex") and Accord Healthcare, Inc. ("Accord" and collectively with Apotex, "Defendants") and Plaintiffs Astellas US LLC, Astellas Pharma US, Inc. and Gilead Sciences, Inc. ("Plaintiffs") have each moved for relief regarding related discovery disputes ("Defendants' Motion" and "Plaintiffs' Motion"). (D.I. 605) The Court[1] has considered the parties' letter briefs, (D.I. 608; D.I. 609; D.I. 623; D.I. 624), and heard argument on February 8, 2021. For the reasons set out below, the Court ORDERS that Defendants' Motion is DENIED and Plaintiffs' Motion is DENIED.

I. DEFENDANTS' MOTION

With their Motion, Defendants seek: (1) a stay of their cases; and (2) an order that Plaintiffs must produce to Apotex certain drug samples that were provided by Accord to Plaintiffs. (D.I. 609) The Court will address in detail only the former request below.[2]

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

[2] As to the latter request regarding the Accord samples, (D.I. 609 at 3), it is premised on the idea that Plaintiffs will use the results of their testing of the Accord samples in the Apotex case, (*id.*). But in their answering brief, Plaintiffs confirm that they will not seek to affirmatively rely on such samples in their case against Apotex, and that Plaintiffs will only seek

When evaluating a potential stay, the Court typically considers: (1) "whether granting the stay will simplify the issues for trial"; (2) "the status of the litigation, particularly whether discovery is complete and a trial date has been set"; and (3) "whether a stay would cause the non-movant to suffer undue prejudice from any delay, or allow the movant to gain a clear tactical advantage." *SenoRx, Inc. v. Hologic, Inc.*, Civ. Action No. 12-173-LPS-CJB, 2013 WL 144255, at *2 (D. Del. Jan. 11, 2013) (citing cases). The Court addresses each factor in turn.

The first "simplification" factor is (at best for Defendants) neutral or (at worst for Defendants) favors Plaintiffs. Defendants argue that the case should be stayed because the drug samples that they have produced to Plaintiffs [redacted] or the "samples") are not representative of the drug that the Defendants have described in their abbreviated new drug application ("ANDA") specifications (i.e., the drug product that is likely to be approved and marketed). (D.I. 609 at 2-3) However, Plaintiffs disagree and assert that these samples *are* representative of what is described in the ANDA specifications; Plaintiffs argue that this is so because the samples were from a batch that was "undisputedly used in [the] ANDA product submitted to the [United States Food and Drug Administration]" [redacted] as indicative of representativeness. (D.I. 623 at 1-2) In taking the position that [redacted] are not representative—and thus that a stay would simplify matters in the case (because a trial that focuses on non-representative samples would be inefficient)—Defendants are really asking the Court to find in their favor on this disputed issue ahead of trial. But that would be inappropriate, as factual and legal disputes about representativeness are issues that (if they exist in an ANDA

to make reference to such samples if Apotex "opens the door by relying on them." (D.I. 623 at 3 & n.8) Therefore, the Court DENIES this request as MOOT.

case) are to be resolved after trial by the trier of fact. *See Merck Sharp & Dohme Corp. v. Amneal Pharms. LLC*, 881 F.3d 1376, 1380-85 (Fed. Cir. 2018); *In re Omeprazole Pat. Litig.*, 490 F. Supp. 2d 381, 495 (S.D.N.Y. 2007). So this factor does not support a stay.

Second, the status of this case is undoubtedly well advanced, which weighs against a stay. The deadline for completion of fact discovery was in October 2020, and expert discovery is set to close in April of this year. (D.I. 469; D.I. 606) And trial is set to happen soon, in June 2021. (D.I. 45) Absent a really good reason to do otherwise, when a case gets this close to trial and the Court and the parties have put this much effort into the litigation, the case is not normally stayed. *See, e.g.*, *Cronos Techs., LLC v. Expedia, Inc.*, C.A. No. 13-1538-LPS, 2016 WL 1089752, at *2 (D. Del. Mar. 21, 2016); *Pragmatus AV, LLC v. Yahoo! Inc*., Civil Action No. 11-902-LPS-CJB, 2013 WL 2372206, at *2 (D. Del. May 30, 2013); (*see also* D.I. 623 at 2-3).

Finally, as to the issue of undue prejudice or tactical advantage, this factor also weighs against staying the case. If a stay were ordered in this case as to these Defendants, then (at least as things stand now) there would have to be two separate trials (i.e., the trial currently scheduled for June 2021, and another trial in the future between Plaintiffs and Apotex and Accord on at least infringement issues). Thus, Plaintiffs would have to wait longer than they otherwise would in order to have closure on whether the asserted patents are valid and infringed by these Defendants. *Cf. Millennium Pharms., Inc. v. Teva Parenteral Meds., Inc*., Civil Action Nos. 09-cv-105, 09-cv-204, 10-cv-137, 2010 WL 1507655, at *3 (D. Del. Apr. 14, 2010). And that would cause some prejudice to Plaintiffs. To be sure, sometimes events occurring late in a case can render a stay necessary, despite any prejudice that stay might cause to the non-movants. But the current record does not support such a decision here.

In sum, with the stay factors favoring Plaintiffs and coming down against Defendants, the Court DENIES Defendants' request for a stay.

II. PLAINTIFFS' MOTION

The Court next turns to Plaintiffs' Motion, in which they request sanctions against Defendants pursuant to Federal Rules of Civil Procedure 11 and 37. Plaintiffs' request is premised on the idea that: (1) Apotex has acted in contravention of the Court's January 4, 2020 discovery dispute-related order by bringing Defendants' Motion, and Apotex has engaged in repeated delay tactics in this case; and (2) Accord has taken a position in pressing Defendants' Motion that is contravened by a prior November 2020 stipulation between Accord and Plaintiffs. (D.I. 608)

Sanctions are "are reserved for the most severe and flagrant violations of the Federal Rules, the law, and the standards of professionalism to which this Court adheres." *Leonard v. Stemtech Int'l, Inc.*, Civ. Action No. 12-86-LPS-CJB, 2012 WL 3655512, at *13 (D. Del. Aug. 24, 2012), *report and recommendation adopted*, 2012 WL 4591453 (D. Del. Sept. 28, 2012). And here, the Court does not have the record to warrant a sanctions finding. With regard to Apotex, the Court agrees with it that in bringing Defendants' Motion, Apotex was not contravening the January 4, 2020 order. (D.I. 624 at 1-2) Nor does the record support the conclusion that Apotex has sought to wrongly delay trial at every turn. (*Id*. at 2-3) As for Accord, it does seem that (as Plaintiffs suggest) the wording of paragraph 1 of the November 2020 stipulation amounts to a concession that Accord will not challenge the representativeness of [redacted] for any reason. (D.I. 572 at 2-3) But although the Court would likely come to that conclusion were it required to decide the issue, it does not think that Accord's contrary position is necessarily *frivolous*. (D.I. 624 at 3)

As such, Plaintiffs' request regarding sanctions is DENIED.

III. CONCLUSION

Therefore, for the reasons set out above, the Court hereby ORDERS that Defendants' Motion is DENIED and that Plaintiffs' Motion is DENIED.

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 **February 17, 2021** 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: February 12, 2021

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