IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC.,	)	
Plaintiffs,	)	REDACTED - PUBLIC VERSION
v.	)	Civil Action No. 19-444-CFC-CJB
CHEMO RESEARCH, S.L., INSUD PHARMA S.L., INTELGENX CORP. and INTELGENX TECHNOLOGIES CORP.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington, Delaware this **11th day of June, 2021**.

WHEREAS, Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. ("Plaintiffs") have filed a Renewed Motion to Stay, (D.I. 346) (the "Motion"), the Court has considered the briefing related thereto, (D.I. 340; D.I. 341; D.I. 342; D.I. 347; D.I. 352; D.I. 354; D.I. 362; D.I. 368), and the Court has further heard argument on June 8, 2021,[1]

NOW, THEREFORE, IT IS HEREBY ORDERED as follows:

1. As an initial matter, the Court notes that it has considered the three stay-related factors: (1) whether a stay will simplify the issues and trial of the case; (2) whether discovery is complete and a trial date has been set; and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. *See CIMA Labs Inc. v. Mylan Pharms., Inc.*,

[1] This case is referred to the Court to resolve all disputes relating to discovery and the protective order. (D.I. 57)

C.A. No. 10-625-LPS, 2011 WL 1479062, at *2 (D. Del. Apr. 18, 2011). Having taken those factors into consideration, the Court HEREBY DENIES the Motion for the reasons that follow.

2. It is apparent that much of Plaintiffs' original focus in the Motion was on the fact that, at the time the Motion was filed: (1) Defendants Chemo Research, S.L., Insud Pharma S.L., Intelgenx Corp. and Intelgenx Technologies Corp. (collectively, "Defendants") had reported that although they had previously expected to file their response to an FDA Complete Response Letter ("CRL") and their amended Abbreviated New Drug Application ("ANDA") by the end of the first quarter of 2021, they would not meet those deadlines, and instead now anticipated submitting the documents by May 15, 2021; (2) it was unclear if Defendants would in fact meet the new May 15, 2021 deadline (in light of the fact that Defendants had missed some prior self-imposed deadlines for making these filings); (3) it was unclear if further FDA action would cause Defendants to have to change their specification regarding the pH ranges for certain layers of film in their proposed generic drug product[2]; and (4) Defendants had not produced nearly all of the anticipated document discovery regarding the CRL. (D.I. 340; D.I. 347) Plaintiffs argued that in light of these uncertainties, the currently scheduled November 15, 2021 infringement trial was untenable, and that the case should be stayed until Defendants obtained "tentative approval [of their ANDA] or it appears likely that [they] will obtain tentative approval but for minor deficiencies." (D.I. 347 at 8) However, since the filing of the Motion, Defendants did, in fact, submit the CRL response and the amended ANDA to the FDA on May 14, 2021. (D.I. 362) By May 18, 2021, Defendants also produced the outstanding document discovery to Plaintiffs (this discovery totaled over 100,000 pages). (D.I. 362; D.I. 368 at 1) And Defendants have also now

[2] The pH ranges of those layers of film are relevant to a key infringement issue in the case.

committed that, no matter what the FDA does from here on out, they will "not change the pH specification [regarding their product] above [redacted][, a level below the range claimed in the patents-in-suit]." (D.I. 368 at 3) So much of the uncertainty that bolstered Plaintiffs' request for a stay has since subsided.

3. Plaintiffs still argue for a stay until the FDA is able to review and weigh in on Defendants' amended ANDA (the FDA has said this will not happen until January 2022 at the earliest). (*See* D.I. 368 at 1; *id.*, ex. 1 at 1) Obviously, if the Court knew that the FDA was likely to (or would in fact) require changes to the pH specification in Defendants' amended ANDA, then that would provide cause for concern. But whether the FDA *will* do that is uncertain. And as Defendants note, there is some level of inherent uncertainty as to the nature of the final accused product in many Hatch-Waxman cases, since the relevant statute provides for pre-FDA approval adjudication of pharmaceutical patent disputes. (D.I. 352 at 6; D.I. 368 at 3 & n.4) Here, the Court is willing to say only that there is *a bit more* uncertainty than in the average case, simply in light of the fact that the FDA has issued a CRL. But the current record does not indicate a level of unpredictability that is so outsized as to warrant a stay. After all, it is not as if in issuing the CRL, the FDA rejected a portion of the original ANDA that set out the proposed pH ranges at issue; instead, the FDA simply asked Defendants to "add a pH specification to its manufacturing process." (D.I. 352 at 1)

4. Moreover, the two cases that Plaintiffs cite for the proposition that the FDA CRL should result in a stay are really inapposite. In a prior opinion, the Court has explained why one of those cases—*Forest Labs., LLC v. Sigmapharm Labs., LLC*, Civil Action No. 14-1119-MSG CONSOLIDATED, 2019 WL 3574249 (D. Del. Aug. 6, 2019)—is not close to being on all fours. (*See* D.I. 193 at 2 n.2) In *Forest Labs.*, a stay was (1) entered on the eve of trial, (2) only

after the district court had extended the case schedule multiple times and (3) only after the defendant had received a *second* CRL from the FDA, which was going to require the defendant to reformulate its drug product in a manner that could impact a key liability issue in the case. 2019 WL 3574249, at *2. As for the other case, *Shire Dev., LLC v. Mylan Pharms., Inc.*, Case No. 8:12-cv-1190-T-36AEP, 2015 WL 10793982 (M.D. Fla. Aug. 11, 2015), the district court stayed the case not only because the generic defendant had received an FDA CRL, but also because just three months before trial that defendant requested a *second and year-long extension* from the FDA in order to respond to the CRL (after having previously pushed back its expected response a number of times). 2015 WL 10793982, at *1-3.

5. In light of the above, this case—one that involves a hard-fought dispute between competitors, and one that has already required a great expenditure of Court resources—should not be paused indefinitely. That said, although the Court has denied the request for a stay, Plaintiffs do make a good argument that the case schedule needs to be altered. Indeed, the current schedule was premised on the idea that Defendants' CRL response would be filed no later than the end of March 2021. But that filing was pushed back by a month and a half. And on top of that, Defendants only just produced over 100,000 pages of new, relevant discovery to Plaintiffs—and did so just three days prior to the close of fact discovery (at a time when no depositions have been taken). (D.I. 305; D.I. 368 at 2) The Court has already requested that the parties provide it with proposals for a new case schedule, and it will enter such a schedule soon.

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 Memorandum Order. Any such redacted version shall be submitted no later than **June 17, 2021** for review by the Court. It should be

accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE