

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIODELIVERY SCIENCES)
INTERNATIONAL, INC. and ARIUS)
TWO, INC.,)

Plaintiffs,)

v.)

Civil Action No. 19-444-CFC-CJB

CHEMO RESEARCH, S.L., INSUD)
PHARMA S.L.U., INTELGENX CORP.)
and INTELGENX TECHNOLOGIES)
CORP.,)

Defendants.)

MEMORANDUM ORDER

At Wilmington, Delaware this **28th day of February, 2020**.

WHEREAS, Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (“Plaintiffs”) have filed a Motion to Stay and Toll the 30-Month Regulatory Stay, (D.I. 132) (the “Stay Motion”), and the Court has considered the briefing related thereto, (D.I. 133; D.I. 151; D.I. 168), and Defendants Chemo Research, S.L., Insud Pharma S.L.U., IntelGenX Corp. and IntelGenX Technologies Corp. (“Defendants”) have filed a Motion to Modify Scheduling Order, (D.I. 152), and the Court has considered the briefing and submissions related thereto, (D.I. 167; D.I. 176; D.I. 185), and the Court further having heard argument on February 18, 2020 (D.I. 187 (hereinafter “Tr.”)):¹

NOW, THEREFORE, IT IS HEREBY ORDERED as follows:

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

1. As an initial matter, the Court HEREBY DENIES Plaintiffs’ Stay Motion. This case concerns, in significant part, the issue of whether Defendants’ ANDA product will infringe Plaintiffs’ patents. Trial as to this issue is set for February 2021—some 11 months away. (D.I. 39 at ¶ 24) And Plaintiffs, as the movants for a stay who have the burden to demonstrate that a stay is warranted, have not yet persuaded the Court that an infringement/noninfringement trial cannot be accomplished in February 2021.²

2. That said, the Court acknowledges Plaintiffs’ concerns about when certain information will become available [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (*id.* at 2). Because these materials relate to

² Plaintiffs argue that this case presents similar circumstances to *Forest Labs., LLC v. Sigmapharm Labs., LLC*, Civil Action No. 14-1119-MSG, 2019 WL 3574249 (D. Del. Aug. 6, 2019), where this Court ordered a stay of an ANDA case, (D.I. 133 at 10-12; D.I. 168 at 2-6; Tr. at 8-9, 11-12, 16-17). The Court disagrees that *Forest Labs* militates in favor of a stay. There, the district court resisted entering a stay of the ANDA litigation until one month prior to trial, and did so only after the generic defendant received its *second* Complete Response Letter (“CRL”) from the United States Food and Drug Administration (“FDA”)—a letter indicating that the defendant would again be required to reformulate its drug product as to a drug property that was central to the infringement case that was about to be tried before the Court. *Forest Labs., LLC*, 2019 WL 3574249, at *2. In those circumstances, this Court entered an emergency stay “to avoid prejudice to [plaintiff] and waste of the Court’s and [plaintiff’s] resources trying infringement of a product the FDA has twice not approved.” *Id.* (internal quotation marks and citation omitted). Here, in contrast, [REDACTED], and 11 months remain until trial. (See D.I. 151 at 17-18) Moreover, [REDACTED] Defendants have submitted a declaration, made under penalty of perjury, from their Vice President of Research and Development, [REDACTED] (D.I. 185 at 1; see also D.I. 186) Put another way, in light of the facts here, *Forest Labs* instructs us that a stay (at least as of now) would be premature.

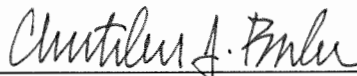
whether Defendants' ANDA product does or does not infringe Plaintiffs' patents, the Court recognizes that they constitute important evidence in this case. At some point, further delays in making these materials available could disrupt an increasingly delicate case schedule. And it follows that if these delays are significant enough, they may eventually necessitate a stay. To that end, the Court HEREBY ORDERS the parties to submit to the Court a joint status letter by no later than May 4, 2020, describing the status of Defendants' production of these materials and the status of discovery as to the infringement/noninfringement case more generally.

3. Finally, because the Court is not moving the trial date as to the infringement/noninfringement case at this juncture, it needs to determine how to adjust the pre-trial schedule as to that case. Here, the Court gave Plaintiffs the opportunity to propose a schedule that would alleviate some of the pressures of simultaneously trying validity/invalidity issues in the combined *Alvogen/Chemo* validity/invalidity trial while preparing expert reports in the infringement/noninfringement case here. (*See* Tr. at 27-28) Plaintiffs declined to do so. (D.I. 185 at 2) Therefore, the Court ADOPTS Defendants' proposed schedule. (D.I. 167 at 1)³

4. 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 **March 4, 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

³ The Court also ADOPTS Defendants' proposed schedule as to the validity/invalidity case. (D.I. 167 at 1) If the Court was to deny Plaintiffs' Stay Motion (which it now has), Plaintiffs did not object to these new deadlines as to the validity/invalidity case. (Tr. at 26) To the extent that there are further disputes as to what is appropriate remaining discovery related to the validity/invalidity case, (*id.*), the Court hopes they can be resolved; if they cannot, the parties may bring them to the Court's attention pursuant to the Court's discovery dispute procedures.

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
UNITED STATES MAGISTRATE JUDGE