

**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.; INTELGENX CORP.; and)
INTELGENX TECHNOLOGIES CORP.,)

Defendants.)

ORDER

At Wilmington, Delaware this **8th day of November, 2019**.

WHEREAS, Plaintiffs Biodelivery Sciences International, Inc. and Arius Two, Inc. (“Plaintiffs”) have moved for relief against Defendants Chemo Research, S.L., Insud Pharma S.L., Intelgenx Corp., and Intelgenx Technologies Corp. (the “Chemo Defendants”) and have asked the Court to “compel [the Chemo Defendants] to provide the pH information requested in [Plaintiffs’] [I]nterrogatory [No. 8] and produce samples of Chemo’s product, even if expired[,]” (D.I. 63 at 3),¹ and the Court has considered the parties’ letter briefs, (D.I. 63, 67), and heard argument on November 4, 2019,

¹ The parties had initially scheduled a discovery conference before District Judge Colm F. Connolly. (Docket Item September 4, 2019) Shortly after, the District Judge referred the case to the Court for all disputes relating to discovery and the protective order. (D.I. 57) In accordance with the Court’s discovery dispute procedures, the parties filed a joint motion seeking resolution of their discovery disputes, (D.I. 62).

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. With regard to Plaintiffs' request that "the Court compel [the Chemo Defendants] to provide the pH information requested in [Plaintiffs'] [I]nterrogatory [No. 8][,]" (D.I. 63 at 3), Plaintiffs' request is GRANTED. Plaintiffs have asked a question in Interrogatory No. 8, and though the Chemo Defendants have twice attempted to answer that question, they have not done so in a sufficient or understandable way. First, the Chemo Defendants, citing to Federal Rule of Civil Procedure 33(d), merely pointed Plaintiffs to their 34,000-plus page ANDA. (D.I. 63, ex. 3 at 13) That was no answer at all. Second, the Chemo Defendants, again citing to Rule 33(d), directed Plaintiffs to certain laboratory notebooks, (D.I. 67, ex. 4 at 3), but it is unclear to the Court exactly how the Chemo Defendants believe that citation to these documents fully answers the question and/or what portions of the documents are said to be relevant and why.

2. Therefore, with the Chemo Defendants having now twice failed to meet the requirements of Rule 33(d), the Court ORDERS that by no later than **November 22, 2019**, the Chemo Defendants shall further supplement their response to Interrogatory No. 8 by providing a narrative answer to each portion of the question. To the extent that the Chemo Defendants cite to documents as part of that narrative answer, they shall clearly explain how such documents provide an answer to all or a portion of the question. Lastly, to the extent that the parties have a dispute about production of certain of the Chemo Defendants' documents relating to certain 2018 testing results, as was referenced during argument on the motion, that issue is not ready for Court resolution. If the parties cannot reach agreement on the issue, they may later avail themselves of the Court's discovery dispute procedures.

3. With regard to Plaintiffs' request that "the Court compel [the Chemo Defendants to] produce samples of Chemo's product, even if expired[,]" (D.I. 63 at 3), the Court first rejects

the Chemo Defendants' argument that the expired samples at issue are irrelevant to Plaintiffs' claims. In a case where there are currently no available unexpired samples of the product the Chemo Defendants intend to market under the ANDA, the Court does not see why Plaintiffs could not attempt to use data from expired samples as some evidence of the content of the to-be-marketed unexpired product. *See Supernus Pharma., Inc. v. TWi Pharma., Inc.*, 265 F. Supp. 3d 490, 509 (D.N.J. 2017); *Mylan Pharma Acquisition Ltd. v. Fresenius Kabi USA, LLC*, No. 15-cv-6700, D.I. 41 (N.D. Ill. March 18, 2016). The Chemo Defendants' arguments about the strength of such evidence, (D.I. 67 at 3), speak more to ultimate issues of proof than they do to relevance.

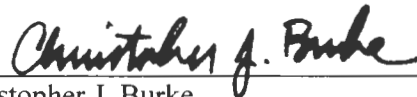
4. That said, the Court does not intend to order the Chemo Defendants to take an action with regard to samples that would violate federal law. The Chemo Defendants have made an (albeit brief) non-frivolous argument that Plaintiffs' request, if granted, would force them to violate federal regulations. (*Id.*)

5. Because the Court has little information from the parties about this legal issue, it hereby ORDERS that by no later than **November 22, 2019**, the parties shall meet and confer regarding this dispute. By that same date, the parties shall submit a joint letter of no more than four single-spaced pages that either:

- (a) indicates that they have resolved the issue; or, if they have not,
- (b) sets out their respective positions as to why federal law does or does not conflict with Plaintiffs' request and what relief the Court could lawfully enter as to this dispute.

6. Because this 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 15, 2019** 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 Order.



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE