

**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 **20th day of February, 2020**.

WHEREAS, Defendants Chemo Research, S.L., Insud Pharma S.L.U., IntelGenX Corp. and IntelGenX Technologies Corp. (“Defendants”) have filed a Motion for Leave to Amend Invalidity Contentions (“Motion”), (D.I. 121), and Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (“Plaintiffs”) oppose the Motion, (D.I. 125), and the Court has considered the parties’ briefs, (D.I. 121; D.I. 134; D.I. 138), and heard argument on February 10, 2020 (D.I. 174, hereinafter “Tr.”):¹

NOW, THEREFORE, IT IS HEREBY ORDERED as follows:

1. With their Motion, Defendants seek to amend their invalidity contentions, in order to add certain defenses pursuant to 35 U.S.C. § 112. (Tr. at 13) Here, in the governing Scheduling Order, the District Court required that if a party seeks to amend its initial

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

infringement or invalidity contentions, it must first make a showing of good cause. (D.I. 39 at ¶ 7); *see also* Fed. R. Civ. P. 16(b)(4). Both parties agree (and the Court agrees) that a movant seeking to show that good cause has been established in this situation would, at a minimum, need to demonstrate that it has acted diligently in moving to amend. (D.I. 121 at 4 (citing *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363-68 (Fed. Cir. 2006); *Bayer Cropscience AG v. Dow AgroSciences LLC*, Civil Action No. 10-1045-RMB-JS, 2012 WL 12904381, at *1 (D. Del. Feb. 27, 2017); D.I. 134 at 5 (citing *O2 Micro*); *see also* D.I. 39 at ¶ 7 (noting, in setting out exemplary showings of good cause, that diligence on the part of the moving party is required))

2. Defendants argue that the impetus for amendment was the District Court's construction of certain claim terms (the "layer terms"); the District Court first informed the parties of its constructions for these claim terms during the December 20, 2019 *Markman* hearing (wherein the District Court adopted Plaintiffs' proposed constructions for the terms). (D.I. 121 at 1; *see also id.*, ex. A at 40) The Court agrees with Plaintiffs (and with the many courts who have concluded the same) that in general, when a party seeks to amend contentions in light of on a district court's claim construction order, "the moving party's diligence, without which there is no good cause, [should be] measured from the day the moving party received the proposed [claim] constructions, not the date of issuance of the Court's claim construction opinion." *Word to Info Inc. v. Facebook Inc.*, Case No. 15-cv-03485-WHO, 2016 WL 6276956, at *4 (N.D. Cal. Oct. 27, 2016) (internal quotation marks and citations omitted) (citing cases), *aff'd*, 700 F. App'x 1007 (Fed. Cir. 2017); *Takeda Pharm. Co. Ltd. v. Sun Pharma Global FZE*, Civil Action No. 14-4616 (MLC), 2016 WL 9229318, at *4-5 (D.N.J. May 16, 2016). This general rule makes good sense, as: (1) if a movant seeks amendment in light of a court's

adoption of a construction that was previously proposed many months earlier; and (2) the movant was nevertheless always found to have acted diligently; then (3) this “would mean that [the moving] party could wait until after the construction to take action, even though [in many cases] they were fully equipped to act sooner.” *Takeda*, 2016 WL 9229318, at *5 (citation omitted). Such an outcome would promote and reward delay and inefficiency, not diligence.

3. Of course, there are scenarios where, even after a *Markman* order issues, a movant’s attempt to amend contentions might still be found to be diligent. One such scenario could be if the district court adopted a construction that had not been proposed by any party—and that new construction was the basis for the subsequent motion to amend. *See Word to Info*, 2016 WL 6276956, at *4-5. Another could arise if a party had earlier put forward a claim construction for a term, but was deliberately vague about the construction’s true meaning or scope (e.g., where the party only made clear the true proposed meaning or scope of the construction during the *Markman* hearing itself).² This latter scenario is what Defendants argue occurred here. Defendants assert that even though Plaintiffs put forward their construction for the layer terms (and provided some explanation in support thereof) on September 13, 2019³ in Plaintiffs’ opening claim construction brief, (D.I. 54), it was not truly until the December 20, 2019 *Markman* hearing “that the full scope and consequences of [Plaintiffs’] arguments [about the layer terms] became apparent.” (D.I. 138 at 2; *see also* Tr. at 7-8)

² There could, of course, be other such similar scenarios.

³ For their part, Plaintiffs note that they served a draft chart with proposed constructions for the layer terms even earlier—on August 27, 2019; they suggest that this is the actual date from which diligence should be measured. (D.I. 134 at 3, 7 & ex. G) The Court, however, will focus herein on the September 13, 2019 date. The Court need not decide whether the August 27, 2019 date is the right “starting point” here, in light of its decision below.

4. The Court is not persuaded by this argument. Prior to claim construction briefing, the parties had proposed constructions for the layer terms, which are found in certain of the patents-in-suit. With their proposed constructions, Defendants asserted that the layer at issue was a “solid” layer; Plaintiffs put forward constructions for the terms that did not include the word “solid.” (D.I. 134, ex. G) Then, in their September 13, 2019 opening claim construction brief, Plaintiffs articulated several supporting rationales for why they took their view. Importantly, they explained there that adding “solid” to the claim term failed to fully capture the covered product described in the specification, which begins “in solid form” but “ultimately erodes or dissolves over time[.]” (D.I. 84 at 10; *see also id.* at 10-11 (“While the mucoadhesive layer is *in solid form*, as opposed to a liquid or a gas, *at stages during the administration to a patient*, there is no reason why this particular feature needs to be added to the claim.”) (emphasis added); Tr. at 30-31, 41-42) Plaintiffs reiterated this same view in their reply claim construction brief, served on October 29, 2019. (D.I. 66) There, they again argued—repeatedly—that even though the layer “is not an aqueous solution[,] [it] does not mean that the word ‘solid’ needs to be read into the claim, *particularly where the layer erodes over time* and the inventors chose to use the word ‘bioerodable’ to define the layer, as opposed to ‘solid.’” (D.I. 84 at 66 (certain internal quotation marks and citation omitted) (emphasis added); *see also id.* at 20, 27) And then, during the December 2019 *Markman* hearing, Plaintiffs’ counsel again made the same point in support of Plaintiffs’ proposed constructions, explaining that “[t]he written description does not refer to a solid bioerodable mucosal layer pretty much because it dissolves. . . [i]t goes away [i]t’s not there after 20 to 30 minutes[.]” (D.I. 121, ex. A at 23; *see also id.* at 38 (Plaintiff’s counsel referring to the layer during the *Markman* hearing as a “bioerodable 50-micron layer that goes away”); Tr. at 43) In sum, so far as the Court can tell, Plaintiffs’ position

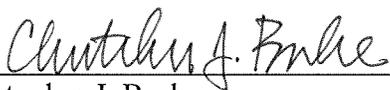
Plaintiffs' position as to the "right" constructions for these terms and their rationale behind these constructions have been evident since September 13, 2019, when Plaintiffs served their opening claim construction brief on Defendants. And Defendants have not otherwise sufficiently explained why this is not so.

5. Having therefore established that Defendants were on notice of the need to move to amend at least as early as September 13, 2019, the Court notes that Defendants did not file this Motion until January 6, 2020. (D.I. 121) Absent the existence of other mitigating circumstances, which are not present here,⁴ this nearly four-month delay demonstrates a lack of diligence on Defendants' part. *See Word to Info*, 2016 WL 6276956, at *6 (finding that a four-to-five-month delay prior to the proposed amendment demonstrated a lack of diligence); *O2 Micro*, 467 F.3d at 1367-68 (affirming a district court ruling concluding that a three-month delay in serving proposed amended contentions amounted to a lack of diligence); *Par Pharm., Inc. v. Takeda Pharm. Co., Ltd.*, Case No. 5:13-cv-01927-LHK-PSG, Case No. 5:13-cv-02416-LHK-PSG, Case No. 5:13-cv-02420-LHK-PSG, 2014 WL 3704819, at *2 (N.D. Cal. July 23, 2014) (finding that a four-month delay showed a lack of diligence); *Acer, Inc. v. Tech. Props. Ltd.*,

⁴ Defendants cite to opinions in a few other cases where a delay of four months (or longer) did not preclude a finding of diligence. (D.I. 121 at 8) However, diligence is a "fact sensitive" inquiry, *see Bayer Cropscience AG*, 2012 WL 12904381, at *1 n.1, and the cases that Defendants cite usually presented some other, mitigating circumstances not present in this case. *See, e.g., Karl Storz Endoscopy-Am., Inc. v. Stryker Corp.*, Case No. 14-cv-00876-RS (JSC), 2016 WL 2855260, at *6 (N.D. Cal. May 13, 2016) (finding that although the movant filed its motion to amend 15 months after initially discovering the prior art references at issue, it had established diligence, but only because the motion was pending for one of those months, the case was stayed for nine of those months, and the movant had notified the opposing party of its intent to amend the contentions immediately when the stay was lifted); *Vasudevan Software, Inc. v. Int'l Bus. Machs. Corp.*, No. C09-05897 RS (HRL), 2011 WL 940263, at *2 (N.D. Cal. Feb. 18, 2011) (concluding that a delay of four months between the amending party's earliest notice of the potential need to amend and the amendment of its contentions was not preclusive, where the party worked diligently throughout that four-month period to confirm its understanding of the technology and its need to amend).

Nos. 5:08-cv-00877 JF/HRL, 5:08-cv-00882 JF/HRL, 5:08-cv-05398 JF/HRL, 2010 WL 3618687, at *4-5 (N.D. Cal. Sept. 10, 2010) (concluding that a party was not diligent in waiting three months after a stay was lifted to begin investigation and another three weeks to file amended infringement contentions); *Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-LHK, 2012 WL 1067548, at *2 (N.D. Cal. Mar. 27, 2012) (finding that a delay of two and one-half months demonstrated a lack of diligence). Accordingly, Defendants' Motion is DENIED.

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 **February 25, 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
UNITED STATES MAGISTRATE JUDGE