IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD, and EGALET US INC.,	:	
Plaintiffs,	:	
	:	Civil Action No. 18-599-CFC
v.	:	
NOVITIUM PHARMA LLC,	:	
Defendant.	:	

MEMORANDUM ORDER

At Wilmington, this 23rd day of September 2019, having reviewed Defendant Novitium Pharma LLC's Motion for Leave to File an Amended Answer and Counterclaims (D.I. 75) and the related briefing (D.I. 76, D.I. 88, D.I. 91), **IT IS HEREBY ORDERED** that Defendant's motion is **DENIED** for the following reasons.

I. BACKGROUND

Plaintiffs iCeutica Pty Ltd and Egalet US Inc. initiated this Hatch-Waxman action on April 20, 2018, accusing Defendant of infringing United States Patent Nos. 9,526,734 (the "#734 patent"), 9,649,318 (the "#318 patent"), and 9,808,468 (the "#468 patent"). D.I. 1 at ¶ 1. The asserted patents cover Plaintiffs' VIVLODEX® brand Meloxicam 5mg and 10 mg capsules for the management of

osteoarthritis pain. *Id.* Defendant has submitted an Abbreviated New Drug Application ("ANDA") "for approval to market [its own] Meloxicam capsules, 5mg and 10mg, before the expiration of the" asserted patents. D.I. 76 at 1.

The deadline for leave to amend pleadings in this case was February 1, 2019. D.I. 31 at ¶ 2. Defendant filed the instant motion on May 7, 2019. *See* D.I. 75. A two-day bench trial is scheduled to begin on February 18, 2019. D.I. 31 at ¶ 18.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 15 governs amendments to the pleadings generally, providing that "[t]he court should freely give leave [to amend] when justice so requires." *See* FED. R. CIV. P. 15(a)(2). When a party moves to amend past the date set by the scheduling order, Federal Rule of Civil Procedure 16(b) also applies. *See* FED. R. CIV. P. 16(b)(4); *see also E. Minerals & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000). In pertinent part, Rule 16(b) provides: "A schedule may be modified only for good cause and with the judge's consent." FED. R. CIV. P. 16(b)(4). "Good cause is present when the schedule cannot be met despite the moving party's diligence." *Meda Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at *1 (D. Del. Nov. 14, 2016). "In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." *S. Track & Pump, Inc. v. Terex Corp.*, 722 F. Supp. 2d 509, 521 (D. Del. 2010) (quotation marks and citation omitted).

If a movant meets its burden under Rule 16(b)(4) to show that good cause exists, the court may then consider whether it should grant leave to amend under Rule 15(a)(2). *See Intellectual Ventures I LLC v. Toshiba Corp.*, 2016 WL 4690384, at *1 (D. Del. Sept. 7, 2016). "The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities." *S. Track & Pump*, 722 F. Supp. 2d at 520 (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990)). Absent a showing of undue delay, bad faith, dilatory motive, prejudice, or futility, leave to amend under Rule 15 should generally be permitted. *Id.* (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

III. ANALYSIS

Defendant requests leave to amend its answer and counterclaims, seeking to assert that the asserted patents are invalid as indefinite under 35 U.S.C. § 112(b). D.I. 76 at 1; *see also* D.I. 75, Ex. A, Proposed Amended Answer at ¶¶ 129–134, Proposed Amended Counterclaims at ¶¶ 42–56. Because Defendant filed its request after the February 1, 2019 deadline to amend pleadings, *see* D.I. 31 at ¶ 2, Defendant must satisfy the good cause requirement of Rule 16(b), *see* FED. R. CIV. P. 16(b)(4). Defendant argues that it satisfies the good cause requirement because Plaintiff did not inform it of Plaintiffs' actual interpretation of the disputed claim

terms until the March 19, 2019 *Markman* hearing.[1] D.I. 76 at 10. In particular, Defendant contends that Plaintiffs' responses to the Court's questions first alerted Defendant to Plaintiffs' position that the disputed claim terms "refer to 'particles' that vaguely '*include* meloxicam,' . . . such that the measurements of median particle size could involve measurement of both meloxicam and various amounts of other things." *Id.* at 10–11 (emphasis in original).

I disagree and find that Defendant has not demonstrated diligence in asserting its new invalidity defenses and counterclaims such that good cause exists to extend the Scheduling Order's February 1, 2019 deadline for pleading amendments. Although Defendant contends that it was not aware of the "full extent to which [Plaintiffs'] interpretation of the claim terms is a moving target" until the *Markman* hearing, *see* D.I. 75 at 10, and that Plaintiffs' intention to pursue this interpretation was not "crystalized" until Plaintiffs' April 3, 2019 written discovery responses, *see id.* at 2, a review of the record informs me otherwise. Plaintiffs' opening claim construction brief, served on December 13, 2018, *see* D.I. 32, discusses how "particle size measurements can be, and in fact

[1] At the March 19, 2019 *Markman* hearing, I construed the first disputed term, "Meloxicam having a median particle size," to mean "a population of Meloxicam particles for which half of the particle diameters are above and the other are below [the] recited [value]." D.I. 86 at 104:9–15. I construed the second disputed term, "Meloxicam having . . . a D(0.9)," to mean "a population of Meloxicam particles for which 90 percent of the particles are below and 10 percent are above [the] recited value." *Id.* at 104:16–19.

are, made on meloxicam particles in the presence of excipients." D.I. 46 at 13. An expert declaration served by Plaintiffs the same day recited: "A person of ordinary skill in the art would . . . understand the particle size measurements described in the '734 parent are not necessarily generated from an 'excipient free' population of meloxicam particles." D.I. 47, Ex. 4 at ¶ 35. Moreover, Plaintiffs' reply brief, although served three days after the deadline to amend pleadings,[2] makes clear Plaintiffs' position that "meloxicam" did not "mean 'pure,' or 'solely,' meloxicam" and "that excipients can exist on the meloxicam structure and therefore be a part of the meloxicam particle." D.I. 46 at 42–43.

Defendants are correct that Plaintiffs' claim construction briefs did not recite the same words Plaintiffs used at the *Markman* hearing to describe their position—*i.e.*, that the amount of meloxicam present in a "meloxicam particle" could be "substantial," "minute," "predominant," or "*de minimis*," among other adjectives. *See* D.I. 91 at 2. But Plaintiffs' position, however presented, was not offered for the first time at that March 19, 2019 hearing. In Defendant's claim construction sur-reply brief, which was served on February 25, 2019, *see* D.I. 45, Defendant

[2] Plaintiffs did not file a notice of service for their reply claim construction brief, but an exhibit attached to Defendant's reply brief informs me that it was served on February 4, 2019. *See* D.I. 91, Ex. 1 (email from K. Kilby to A. Burgy, et al. (Feb. 4, 2019)).

itself attributed to Plaintiffs the very position Defendant now contends it learned for the first time at the *Markman* hearing:

> Under [Plaintiffs'] construction, the pharmaceutical composition need not contain 5 mg of meloxicam, so long as the "meloxicam particles"—which can comprise an indefinitely high percent of excipients—have a collective total mass of 5 mg. That means that, under Plaintiffs' construction, the "5 mg of meloxicam" limitation would be met by a composition containing nowhere near 5 mg of the active ingredient (e.g. a composition that contains *0.0005 mg* of the active ingredient would meet that limitation, so long as the remainder of the excipient-containing particle's 5 mg mass is made up of excipients).

D.I. 46 at 70 (emphasis in original).

I am therefore not convinced that Defendant was unaware of Plaintiffs' position until the *Markman* hearing. Although it might be the case that Defendant acted diligently after the *Markman* hearing to amend its pleadings,[3] Defendant has not shown that it acted diligently before the hearing.[4] Moreover, despite Defendant's assertion that "[c]laim construction rulings can establish good cause

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[3] To be clear, I am not making a determination as to Defendant's diligence after the *Markman* hearing. But, as Defendant notes, it did take several steps in asserting its proposed invalidity defenses and counterclaims, such as notifying Plaintiffs and the Court that it would likely seek to amend its pleading to assert indefiniteness as well as seeking to meet and confer with Plaintiffs. *See* D.I. 75 at 7–10; *see also* D.I. 86 at 71:11–15. That being said, I will note that, despite making its intent to amend known at the *Markman* hearing, Defendant still waited an additional eight (8) weeks to file the instant motion.

[4] Defendant offers that it served Plaintiffs with written discovery less than a week after the parties filed their joint claim construction brief. *See* D.I. 76 at 6; *see also* D.I. 48 (notice of service for Defendant's written discovery). This service, however, occurred almost four weeks after Plaintiffs served their reply claim construction brief, which clearly put Defendant on notice of Plaintiffs' position.

for leave to amend to add new invalidity positions," *see* D.I. 76 at 17, parties "have an obligation 'to prepare for the fact that the court may adopt the other party's claim construction.'" *St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 2012 WL 1015993, at *5 (alteration adopted); *see also Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 270 F. Supp. 2d 519, 524 (D. Del. 2003).[5] Defendant's decision to wait until after the hearing was a tactical decision. Such "[a] strategic mistake does not equate to a showing of good cause under Rule 16." *St. Clair Intellectual Prop.*, 2012 WL 1015993, at *6. Accordingly, I will deny Defendant's request for leave to amend its answer and counterclaims.[6]

COLM F. CONNOLLY,
UNITED STATES DISTRICT JUDGE

[5] Defendant proposed that both disputed terms be construed to contain an "excipient-free" limitation. *See* D.I. 29, Ex. A.

[6] Because I have denied Defendant's motion based on its failure to demonstrate good cause under Rule 16(b)(4), I need not reach the parties' Rule 15 arguments. *See Meda Pharm.*, 2016 WL 6693113, at *2 n.2.