

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS
INTERNATIONAL GMBH and
TEVA PHARMACEUTICALS
USA, INC.,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

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Civil Action No. 18-cv-12029-ADB

MEMORANDUM AND ORDER

BURROUGHS, D.J.

In this patent infringement suit, Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”) allege that Eli Lilly and Company’s (“Lilly”) product Emgality, with the active ingredient galcanezumab, has infringed Teva’s patents, including U.S. Patent Nos. 8,586,045 (the “’045 Patent”); 9,884,907 (the “’907 Patent”); and 9,884,908 (the “’908 Patent”) (collectively, the “patents-in-suit”). [ECF No. 1]. The patents-in-suit are related to a treatment for migraines that is marketed under the brand name Ajovy. [Id. ¶ 4].

Currently before the Court are Teva’s motion for sanctions, [ECF No. 143], Lilly’s motion to exclude Teva’s rebuttal expert Dr. Geoffrey Hale, [ECF No. 181], and Lilly’s motion to amend its answer, [ECF No. 175]. For the reasons set forth below, (1) the motion for sanctions is DENIED; (2) the motion to exclude Dr. Hale is DENIED but Dr. Hale is ORDERED not to disclose any of Lilly’s confidential information or work product to Teva; and (3) Lilly’s motion to amend its answer is GRANTED.

I. TEVA'S MOTION FOR SANCTIONS

A. Background

On August 18, 2021, Teva moved to impose sanctions on Lilly pursuant to Federal Rule of Civil Procedure 37(b), arguing that sanctions are warranted because Lilly did not apply the proper search terms when collecting documents in violation of the Court's March 8, 2021 Order (the "March 8 Order"). [ECF No. 143].

The March 8 Order resolved a discovery dispute that Teva raised in a letter filed with the Court. In its letter, Teva asked the Court to compel Lilly to run the following two searches:

1. galca* OR gmab OR 2951742 OR L2951742 OR Y2951742 OR LY2951742 OR LLY2951742 OR LSN2951742 OR **[any internal project o[r] code names used by Lilly]**
2. CGRP* AND ((Jan w/2 Benschop* OR [email address of Jan Benschop]) OR (Barrett w/2 Allan* OR [email address of Allan Barrett]) OR (Mark w/2 Chambers* OR [email address of Mark Chambers]) OR (Ryan w/2 Darling OR [email address of Ryan Darling]) OR (Donald w/2 Gehlert* OR (Kalpana w/2 Merchant* OR [email address of Kalpana Merchant]) OR (Armen w/2 Shanafelt* OR [email address of Armen Shanafelt]))

[ECF No. 99-4 at 1 (emphasis added)]. The March 8 Order, in relevant part, states that

[t]he parties have submitted several discovery disputes for the Court's consideration via letter/requests . . . **Lilly is ordered to perform a search using the phrase "galca," as described in Teva's letter/request.** [ECF No. 99]. As Teva notes, this is not a product name (Emgality) but is the name of the active ingredient antibody in that product and is therefore highly relevant to this litigation despite the relative burden that running the search may impose on Lilly. As to the second search string that Teva discussed in its letter/request, Lilly represents that it has already agreed to run it, so that issue is moot. [ECF No. 103 at 1].

[ECF No. 104 (emphasis added)].

The parties now disagree about which internal project or code names Lilly needed to include in its search to comply with the March 8 Order. Teva argues that the terms [REDACTED]

[REDACTED] are "internal project o[r] code names used by Lilly" and therefore Lilly

had to include those terms when it ran Search Term No. 1. [ECF No. 144 at 8–9 (alteration in original)]. Lilly responds that it did not search for the terms [REDACTED] because, in its view, they are not internal project or code names. [ECF No. 151-3 at 12].

Because Teva has already taken fact depositions without the benefit of the relevant responsive materials, it asserts that ordering Lilly to perform the search now is insufficient and more severe sanctions are warranted. [ECF No. 144 at 21–22]. Teva proposes the following sanctions:

1. The Court enter a finding that Lilly’s accused galcanezumab antibody (or the therapeutic use thereof) meets each and every limitation of the asserted claims of the patents-in-suit, either literally or under the doctrine of equivalents;
2. Lilly be precluded from arguing that [REDACTED]
3. Lilly be precluded from relying on documents it produced during the litigation to support its § 112 defenses;
4. The jury be provided with an instruction that they may apply an adverse inference that Lilly failed to produce early development documents about galcanezumab because such documents would be detrimental to Lilly’s non-infringement and § 112 defenses; and
5. Lilly be ordered to pay Teva’s attorney’s fees associated with preparing and litigating this motion.

[Id. at 22]. While Teva asserts that these sanctions are an appropriate remedy, it requests that, at minimum, Lilly be ordered (1) to search for and produce relevant documents with the terms [REDACTED]; (2) produce any witnesses for further depositions at Teva’s request; and (3) pay Teva’s attorney’s fees associated with litigating this motion, reviewing the newly produced documents, and re-deposing any witnesses. [Id. at 22–23].

Lilly opposed the motion for sanctions on September 1, 2021. [ECF No. 151]. Teva filed its reply on September 15, 2021, [ECF No. 161], and Lilly filed a sur-reply on September 23, 2021, [ECF No. 171].

B. Legal Standard

Under Rule 37(b)(2),

[i]f a party or a party’s officer, director, or managing agent—or a witness designated under Rule 30(b)(6) or 31(a)(4)—fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders.

Fed. R. Civ. P. 37(b)(2)(A). These “just orders” include various sanctions, such as dismissal of claims and defenses or accepting factual inferences in favor of the moving party. Id. “The imposition of sanctions under Rule 37(b) is left to the discretion of the trial court.” Patel v. 7-Eleven, Inc., No. 17-cv-11414, 2020 WL 6940124, at *2 (D. Mass. June 24, 2020) (citing Ruiz v. Principal Fin. Grp., No. 12-cv-40069, 2014 WL 257429, at *5 (D. Mass. Jan. 22, 2014)). Rule 37(b), however, “contemplate[s] a threshold determination by the court that the offending party has failed to comply with a court order. . . .” Ortiz-Lopez v. Sociedad Espanola de Auxilio Mutuo Y Beneficiencia de Puerto Rico, 248 F.3d 29, 33 (1st Cir. 2001). Accordingly, the Court must first determine if Lilly ignored its obligations under the March 8 Order.

C. Discussion

Teva argues that the March 8 Order required Lilly to search for [REDACTED] because the Order directed Lilly to perform a search “as described in Teva’s letter/request,” and the search that Teva proposed in its letter clearly considered [REDACTED] to be internal project or code names. [ECF No. 144 at 13–14]. Though Teva argues that the Court adopted its interpretation of “internal project o[r] code names,” such a conclusion is not supported by the record. The parties’ briefing on disputes concerning Search Term No. 1 focused on whether the term “galca*” would lead to relevant discovery and the burden it would impose on Lilly. [ECF No. 99-4 at 3 (Teva’s letter stating that “[t]he only dispute as to Search Term No. 1 is whether to include the name of the active ingredient in Lilly’s

infringing Emgality® product, as set forth below. Specifically, the parties dispute whether Lilly should have to search for “galca*,” which would encompass “galcanezumab” and variations thereof.”); ECF No. 103 at 2 (“Lilly had already agreed to independently run each of the above terms, except for ‘galca*’ . . .”). The briefing did not squarely address the meaning of the term “internal project o[r] code names used by Lilly” as used in Search Term No. 1. In fact, the only discussion of the term “internal project o[r] code names” as used in Search Term No. 1 was Teva’s statement, in a footnote, that documents “indicate” that [REDACTED] [REDACTED] were project names used by Lilly. [ECF No. 99-4 at 3 n.3].¹ Thus, the March 8 Order responded to the dispute that was briefed and presented to the Court (i.e., whether Lilly must search the term “galca*”), but did not incorporate arguments put forth by Teva that were unrelated to that issue.

Accordingly, the Court never clearly adopted the position that Teva advanced in its footnote (i.e., that [REDACTED] are internal project or code names used by Lilly), and without a clear finding on the definition of that term, it cannot be said that Lilly disregarded the Court’s order. Therefore, because there was no violation of a Court order, there are no grounds for imposing any sanctions and Teva’s motion is DENIED.

II. LILLY’S MOTION TO EXCLUDE

Pursuant to the amended Scheduling Order in this case, the parties exchanged opening expert reports on September 16, 2021. [ECF No. 128 at 3 (proposed amended schedule); ECF

¹ Although Teva’s briefing on Search Term No. 2 argued that internal Lilly documents “refer[red] to the development project that led to galcanezumab as [REDACTED] [REDACTED] [ECF No. 99-4 at 5], the dispute over Search Term No. 2 was moot, and the Court therefore did not determine the relevance of the terms [REDACTED] in that context, [ECF No. 104 (Court’s order stating “[a]s to [Search Term No. 2] that Teva discussed in its letter/request, Lilly represents that it has already agreed to run it, so that issue is moot.”)].

No. 129 (Court's order adopting proposed amended schedule)]. The next day, September 17, 2021, Teva disclosed Dr. Geoffrey Hale as a rebuttal expert. [ECF No. 183-6 at 1]. Lilly objected to Teva's disclosure because Dr. Hale has previously performed work for Lilly relating to antibody development, [ECF No. 183-7 at 1], and has now moved to exclude Dr. Hale as an expert. [ECF No. 181].

A. Factual Background

Dr. Hale is an expert in the field of antibody development, which includes the humanization of antibodies. [ECF No. 192-1 ¶ 1]. Currently he is the CEO of mAbsolve, the managing director of Bioarchitech, and a freelance scientist and consultant. [Id.]. Over the last decade, as a freelance consultant, he has consulted for approximately forty-five companies on more than sixty projects that all related to antibody development, including antibody humanization. [Id. ¶ 2]. In 2012 and then again in 2018, Dr. Hale consulted for Lilly in the area of [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. The March 2012 Engagement

[REDACTED]

2. The 2017–2018 Engagement

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

On October 12, 2021, Lilly filed its motion to exclude Dr. Hale as an expert in this litigation based on his prior work for Lilly. [ECF No. 181]. In the alternative, Lilly requests that the Court prohibit Dr. Hale from disclosing Lilly’s confidential material and protected work product pursuant to his signed engagement letters. [ECF No. 182-1 at 19]. Teva opposed the motion on October 19, 2021, [ECF No. 190-1], and Lilly replied on October 25, 2021, [ECF No. 208-1].

B. Legal Standard

“Although courts are generally reluctant to disqualify expert witnesses, federal courts have inherent authority to disqualify experts if necessary to preserve public confidence in the fairness and integrity of the judicial system.” Palomar Med. Techs., Inc. v. Tria Beauty, Inc., No. 09-cv-11081, 2012 WL 517532, at *2 (D. Mass. Feb. 15, 2012) (quoting Lacroix v. Bic Corp., 339 F. Supp. 2d 196, 199 (D. Mass. 2004) (internal quotation marks omitted)). When analyzing a motion to disqualify, “[t]he court must determine whether, (1) it was objectively reasonable for the moving party to believe that it had a confidential relationship with the expert; and (2) whether the moving party disclosed confidential information to the expert *that is relevant to the current litigation.*” Lacroix, 339 F. Supp. 2d at 199–200 (emphasis added). “Confidential information essentially is information ‘of either particular significance or [that] which can be readily identified as either attorney work product or within the scope of the attorney-client privilege.’” Id. at 200–01 (quoting Hewlett–Packard Co. v. EMC Corp., 330 F. Supp. 2d 1087, 1094 (N.D. Cal. 2004)) (alteration in original). Confidential information could include

discussion of the party’s “strategy in the litigation, the kinds of experts [the party] expected to retain, [the party’s] view of the strengths and weaknesses of each side, the role of each of the [party’s] experts to be hired and anticipated defenses.”

Id. at 201 (quoting Hewlett–Packard, 330 F. Supp. 2d at 1094; Mayer v. Dell, 139 F.R.D. 1, 4 (D.D.C. 1991)) (alterations in original). The party seeking disqualification bears the burden of demonstrating that a confidential relationship existed and relevant confidential information was disclosed. Palomar Med. Techs., Inc., 2012 WL 517532, at *2.

C. Discussion

Lilly contends that Dr. Hale must be disqualified because it had a confidential relationship with him and during the course of that relationship provided him with privileged and confidential information that is relevant to this litigation. [ECF No. 182-1 at 13–17].

First, the Court agrees, and Teva does not dispute, [ECF No. 190-1 at 17], that Lilly and Dr. Hale entered into a confidential relationship. In the 2012 and 2017 engagements, [REDACTED]

[REDACTED] Lilly “reasonably . . . expect[ed] that any communications would be maintained in confidence.” LaCroix, 339 F. Supp. 2d at 200 (quoting Hewlett-Packard, 330 F. Supp. 2d at 1093).

Second, Lilly asserts that Dr. Hale received confidential and privileged information in his prior engagements that is relevant to the issues he would opine on in this case. [REDACTED]

[REDACTED] Dr. Hale’s receipt of privileged or confidential information during his prior consultancies does not merit disqualification. The facts here are similar to those in LaCroix v. Bic Corp., 339 F. Supp. 2d 196 (D. Mass. 2004). In LaCroix, the plaintiff, after being injured by a lighter explosion, sued the

lighter manufacturer and retained an expert in fire dynamics. Id. at 198. The manufacturer moved to disqualify the plaintiff's expert on the grounds that the expert had previously provided the manufacturer with consultant/expert witness services in connection with another lawsuit. Id. at 198–99. During that consultancy, the manufacturer disclosed information relating to its “lighter manufacturing processes, testing and litigation strategy.” Id. at 198. It was undisputed that, at the time of the lawsuit, the manufacturer and the expert had not had any contact for several years. Id. at 199. The court found that the expert and the manufacturer had entered into a confidential relationship and that the expert was precluded from using any confidential or proprietary information that he had obtained during that relationship. Id. at 201. It further concluded, however, that there was “little or nothing in the way of confidential information relevant to the current litigation to which [the expert] was exposed,” in part, because it was “undisputed that the parties never communicated on matters of any substance relating to the specifics of this case.” Id. at 201. The expert was not disqualified. Id.

Here, as with the expert in LaCroix, “the parties never communicated on matters of any substance relating to the specifics of this case.” LaCroix, 339 F. Supp. 2d at 201.³ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ Lilly seeks to distinguish LaCroix because it was a products liability case where the expert had broad expertise in fire safety, as opposed to Dr. Hale's specialized and narrow expertise in [REDACTED]

[REDACTED] See CreAgri, Inc. v. Pinnacliffe Inc., No. 11-cv-06635, 2013 WL 6700395, at *6 (N.D. Cal. Dec. 18, 2013) (finding that discussions of topics that “have no relation to the patents-in-suit or this litigation” are not evidence of confidential information); H. Lundbeck A/S v. Apotex Inc., No. 18-cv-0088, 2020 WL 1285834, at *2 (D. Del. Mar. 18, 2020) (noting that even accepting that the expert received confidential and privileged information during previous engagements, the court was “not persuaded that the information [the expert] received in decade-old litigations involving different drugs would require his disqualification” and “nothing in the record suggests that [the expert] was privy to any privileged information other than the trial strategy used” in the previous cases); Chamberlain Grp., Inc. v. Interlogix, Inc., No. 01-cv-6157, 2002 WL 653893, at *4 (N.D. Ill. Apr. 19, 2002) (“[A]n expert’s exposure to trial strategy in an unrelated and different action is insufficient to warrant the extreme sanction of disqualification.”).

Accordingly, Lilly’s motion to exclude Dr. Hale is DENIED. Although Dr. Hale may continue to serve as an expert, [REDACTED]

[REDACTED] Dr. Hale is ORDERED not to disclose any confidential information or work product [REDACTED]

III. LILLY’S MOTION TO AMEND ITS ANSWER

Lilly moves to amend its answer to add factual allegations and assert additional counterclaims and affirmative defenses based on inequitable conduct in connection with the ’045, ’907 and ’908 patents. [ECF No. 176-4 at 6; ECF No. 176-6 at ¶¶ 187–307].⁴ Lilly

⁴ When citing to Lilly’s proposed amended answer, all citations are to the paragraphs in the amended counterclaims section.

contends that amending the answer is warranted because discovery revealed that individuals, including the named inventors of the patents-in-suit, materially misled the U.S. Patent and Trademark Office (“PTO”) by making false statements and failing to disclose information during prosecution of the relevant patent applications. [ECF No. 176-4 at 7–10].

A. Lilly’s Inequitable Conduct Allegations

The patents-in-suit are directed to treating migraines and other vasomotor symptoms caused by calcitonin gene-related peptide (“CGRP”) by using antibodies that bind to CGRP to inhibit its function. [ECF No. 176-4 at 7]. CGRP has different regions to which an antibody might bind, including the mid-region, the C-terminal region on one end, and the N-terminal region on the other end. [ECF No. 176-6 ¶ 190]. The relevant patent applications that led to the patents-in-suit included broad claims that did not describe the different CGRP regions or note what antibody structure would be required to treat migraines and vasomotor symptoms. [Id. ¶ 191]. Lilly alleges that “[b]ut for . . . persistent concealment” and misleading statements, such broad claims would never have issued. [Id. ¶ 266]. Lilly’s proposed amended answer and briefing in support focuses on the following conduct:

- Before the filing of the November 2, 2006 non-provisional application (the “2006 PCT Application”), named inventors, [REDACTED] were aware that [REDACTED]. [ECF No. 176-4 at 23–24; ECF No. 176-6 ¶¶ 193, 216, 220].
- Before the relevant provisional patent application was filed on November 14, 2005, at least [REDACTED] was aware of a prior art reference (“the Shaw Reference”) that demonstrated that an antibody that bound to CGRP’s mid-region, actually “fail[ed] to block and even enhance[d] the action of CGRP.” [ECF No. 176-6 ¶ 192 (quoting the Shaw Reference) (first alteration in original); ECF No. 176-4 at 23–24]. The Shaw Reference was eventually disclosed during the prosecution of the ‘907 and ‘908 patents, but was “buried” in a list with 409 other references. [ECF No. 176-6 ¶ 197].

- During the prosecution of the '045 patent, the PTO rejected the pending claims for lack of enablement. [ECF No. 176-6 ¶ 259]. In response, patent agent Dr. Jeffrey C. Giering filed a response stating that because C-terminal-binding antibodies treat vasomotor symptoms, “any antibody that effectively binds CGRP may reasonably be expected to have the claimed effect.” [ECF No. 176-6 ¶ 260; ECF No. 176-4 at 23–24]. Lilly alleges that this was a false statement. [ECF No. 176-6 ¶ 261].
- [REDACTED] did not disclose that [REDACTED] [ECF No. 176-4 at 9; ECF No. 176-6 ¶¶ 285, 289, 291–95].

B. Legal Standard

Under Federal Rule of Civil Procedure 15(a), a party may amend its pleading once as a matter of course within twenty-one days after serving it or, if the pleading is one to which a responsive pleading is required, within twenty-one days after a motion to dismiss or answer has been filed. Fed. R. Civ. P. 15(a)(1). Otherwise, a party may only amend the pleading “with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). Rule 15 instructs that leave to amend should be “freely give[n] . . . when justice so requires.” *Id.* “At a certain point,” however, “this amendment-friendly regime may cease to govern.” *U.S. ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 192 (1st Cir. 2015).

In cases where a district court has issued a scheduling order under Rule 16(b) and the amendment sought contravenes a deadline imposed by the court, “Rule 16(b)’s more stringent good cause standard supplants Rule 15(a)’s leave freely given standard.” *D’Agostino*, 802 F.3d at 192 (first citing *Cruz v. Bristol-Myers Squibb Co., P.R., Inc.*, 699 F.3d 563, 569 (1st Cir. 2012), then citing *Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 327 (1st Cir. 2008)). “If [the Court] considered only Rule 15(a) without regard to Rule 16(b), [it] would render scheduling orders meaningless and effectively would read Rule 16(b) and its good cause requirement out of the Federal Rules of Civil Procedure.” *Sosa v. Airprint Sys., Inc.*, 133 F.3d

1417, 1419 (11th Cir. 1998); see also O’Connell v. Hyatt Hotels of P.R., 357 F.3d 152, 155–56 (1st Cir. 2004) (citing Sosa with approval).

“Rule 16(b)’s ‘good cause’ standard emphasizes the diligence of the party seeking the amendment.” O’Connell, 357 F.3d at 155. Under this inquiry, “[p]rejudice to the opposing party remains relevant but is not the dominant criterion.” Id. Rather, “[i]ndifference’ by the moving party” may preclude leave to amend “irrespective of prejudice because such conduct is incompatible with the showing of diligence necessary to establish good cause.” Id. (citation omitted). “Particularly disfavored are motions to amend whose timing prejudices the opposing party by ‘requiring a re-opening of discovery with additional costs, a significant postponement of trial, and a likely major alteration in trial tactics and strategy’” Steir v. Girl Scouts of the USA, 383 F.3d 7, 12 (1st Cir. 2004) (quoting Acosta-Mestre v. Hilton Int’l of P.R., Inc., 156 F.3d 49, 52 (1st Cir. 1998)). “As a case progresses, . . . the burden on a plaintiff seeking to amend a [pleading] becomes more exacting.” Id.

In addition to good cause, futility presents another potential bar to amendment. In the context of a motion to amend, “futility means that the complaint, as amended, would fail to state a claim upon which relief could be granted.” O’Leary v. N.H. Boring, Inc., 323 F.R.D. 122, 126 (D. Mass. 2018) (citing Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996)). “If leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the ‘futility’ label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).” Hatch v. Dep’t for Children, Youth & Their Families, 274 F.3d 12, 19 (1st Cir. 2001). Under this standard, an amendment will not be deemed futile unless it fails to support a “plausible entitlement to relief.” Rodríguez-Ortiz v.

Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007)).

C. Discussion

Under the original scheduling order, the deadline for amendments to the pleadings was March 22, 2021. [ECF No. 46]. Because the amended scheduling orders extending the discovery deadlines made no reference to a new deadline for amended pleadings, all amendments to pleadings should have been filed by March 22, 2021. Given the untimeliness of the motion to amend, the Court reviews the request under Rule 16(b)'s "good cause" standard, which is based on diligence and prejudice to the non-moving parties, and also considers the futility of the proposed amendment.

1. Diligence

Lilly maintains that it was diligent in seeking leave to amend its answer because it was Teva's February 26, 2021 document production that first "suggested" that [REDACTED] and it was not until August 2021, during the depositions of the named inventors, that the "full factual information supporting Lilly's new grounds of unenforceability due to inequitable conduct was fully revealed." [ECF No. 176-4 at 11–16, 19–21].

The key discovery Lilly needed to develop its potential inequitable conduct claim related to the early development of the patents-in-suit by the named inventors. [ECF No. 176-4 at 11, 13–14, 19]. On March 8, 2021, Lilly wrote to Teva regarding the small number of early development documents produced to date. [ECF No. 177-13 at 2–3]. On April 6, 2021, Teva notified Lilly that, as of April 2, 2021, it had produced all relevant, non-privileged early development documents in its control. [ECF No. 177-14 at 2–3]. Teva also explained that "[i]f Lilly remains unsatisfied with the volume and/or type of [REDACTED] documents Teva has

produced to date, Lilly is free to seek additional documents from [REDACTED] directly.”⁵ [Id. at 3]. Lilly also represents that on May 4, 2021, Teva confirmed that it had substantially completed its production of non-privileged documents for the named inventors. [ECF No. 176-4 at 14]. In response to Teva’s representations, on May 5, 2021, Lilly served subpoenas and deposition notices on the named inventors to obtain additional information about early development documents. [Id. at 14–15; ECF No. 177-15 at 2]. Lilly also served [REDACTED] with a document subpoena on or around May 17, 2021. [ECF No. 176-4 at 15; ECF No. 222-1]. Third-party document production took place from June 30, 2021 to August 5, 2021, and the named inventors’ depositions took place from July 30, 2021 to August 20, 2021. [ECF No. 176-4 at 15–16; ECF No. 177-17]. Privilege logs were served on September 28, 2021. [ECF No. 176-4 at 15].

Teva does not argue that Lilly actually knew of a potential inequitable conduct claim prior to February 2021, and instead asserts that Lilly could have learned of the underlying facts sooner if it had diligently sought them. [ECF No. 207-1 at 7]. According to Teva, the parties’ August 2020 correspondence demonstrates that Lilly knew that it needed to, and was in fact planning to, reach out to [REDACTED] to obtain documents, but did not serve a document subpoena on [REDACTED] until May 2021. [Id. (citing to August 2020 emails where Lilly stated that it “intends to correspond directly with [REDACTED] regarding early development documents); ECF No. 177-8 at 2]. Although Lilly certainly could have subpoenaed [REDACTED] and the named inventors earlier, Teva does not compellingly address the fact that it was its own February 26, 2021 document production that first alerted Lilly to a potential inequitable conduct claim. Because the documents produced in February 2021 were in its possession, custody, and control, Teva’s own

[REDACTED]

delay in producing them contributed to Lilly's delay in learning of a potential inequitable conduct defense. Thus, the Court cannot conclude that Lilly's late discovery of a potential inequitable conduct defense was attributable solely to its own lack of diligence or evidence of indifference.

Accordingly, the Court focuses on whether Lilly's decision to move to amend in October 2021 was diligent accepting that it first learned of a potential claim in February 2021. Fundamentally, the Court agrees that given the heightened pleading standard for inequitable conduct claims, see Section III.C.2 infra, it was reasonable for Lilly to further develop its claim through deposition testimony before moving to amend. Although there was an eight-month delay in filing the motion, there was only a few-week delay between Teva's confirmation that it would not be producing any additional early development or named inventor documents and Lilly serving third-party discovery. This short delay does not manifest indifference. Third-party depositions, document productions, and privilege logs were not completed until September 28, 2021, and the motion to amend was filed approximately a week later. Again, this relatively brief delay between the completion of third-party discovery and the filing of the motion to amend is not evidence of a lack of diligence. In sum, the Court credits Lilly's assertion that it did not know enough about any alleged inequitable conduct until after discovery progressed and finds the delay in bringing this motion to be the result of a slow discovery process rather than bad faith or indifference. See Penobscot Nation v. Mills, No. 12-cv-00254, 2014 WL 442429, at *3 (D. Me. Feb. 4, 2014) ("Defendant's request to amend does not reflect delay, rather it reflects the developing factual record related to this litigation.").

While Rule 16(b)'s "good cause" standard "focuses on the diligence (or lack thereof) of the moving party more than it does on any prejudice to the party-opponent," Somascan, Inc. v.

Philips Med. Sys. Nederland, B.V., 714 F.3d 62, 64 (1st Cir. 2013) (quoting Flores-Silva v. McClintock-Hernández, 710 F.3d 1, 3 (1st Cir. 2013)), prejudice is still a factor to be considered. Teva does not argue that it will be prejudiced by Lilly’s proposed amended answer, and Lilly represents that there would be no prejudice to Teva if the late amendment is allowed because no further discovery will be needed beyond the contemplated expert discovery and that the case scheduling order will not need to be altered. [ECF No. 176-4 at 21–22]. In light of these representations and Teva’s silence on the issue, the Court finds that the amendment will not unduly prejudice Teva.

Accordingly, there is good cause for Lilly’s late-filed motion to amend.

2. Futility

Even though Lilly was diligent, Teva argues that the amendment is futile because the proposed amended pleading fails to state an inequitable conduct claim. “Inequitable conduct is an equitable defense that prevents enforcement of a patent obtained through fraud.” Lexington Luminance LLC v. Osram Sylvania Inc., 972 F. Supp. 2d 88, 91 (D. Mass. 2013). An inequitable conduct defense must satisfy the requirements for alleging fraud set forth in Federal Rule of Civil Procedure 9(b). Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326–27 (Fed. Cir. 2009). In determining “whether inequitable conduct has been pleaded with particularity under Rule 9(b),” the law of the Federal Circuit applies. Id. at 1326. “The [Federal Circuit] [has] tightened the inequitable conduct [pleading] standard to ensure that the defense is sustained only in egregious circumstances and to discourage parties from using it as a mere litigation tactic in garden-variety cases.” PetEdge, Inc. v. Fortress Secure Sols., LLC, No. 15-cv-11988, 2016 WL 407065, at *3 (D. Mass. Feb. 2, 2016) (quoting Lexington Luminance LLC, 972 F. Supp. 2d at 91) (alterations in original). “A pleading that simply avers the substantive

elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” Exergen Corp., 575 F.3d at 1326–27 (citation omitted). Thus, “in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” Id. at 1327.

Although Rule 9(b) requires particularity, “[m]alice, intent, knowledge, and other conditions of mind of a person may be averred generally.” Exergen Corp., 575 F.3d at 1327 (quoting Fed. R. Civ. P. 9(b)) (alteration in original). “The relevant ‘conditions of mind’ for inequitable conduct include: (1) knowledge of the withheld material information or of the falsity of the material misrepresentation, and (2) [a] specific intent to deceive the PTO.” Id. To satisfy this standard, the pleading “must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” Id. at 1328–29.

Teva avers that Lilly’s proposed amended answer is futile because it (1) generally ascribes conduct to “the Applicants” rather than to any specific person; (2) does not contain facts sufficient to show that the false or withheld information was material or known to be material; and (3) ignores that a specific individual has to act with a deliberate intent to deceive. [ECF No. 207-1 at 11–23].

First, Teva is correct that many of Lilly’s allegations in its proposed amended answer do not refer to a specific individual and instead refer to “Applicants,” which is defined in Count XIX of the proposed amended answer, as

the applicants, their attorneys, and/or their agents, and/or the person(s) involved in the preparation and/or prosecution of that patent, including without limitation,

Labrys Biologics, Inc. (“Labrys”), attorneys at Wilson Sonsini Goodrich & Rosati, including, Adam J. Cole (patent agent at Wilson Sonsini Goodrich & Rosati), and Jeffrey C. Giering (former patent attorney at Wilson Sonsini Goodrich & Rosati) (collectively, “WSGR Counsel”), Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), and Teva Pharmaceuticals International GmbH

[ECF No. 176-6 ¶ 141]. Lilly disputes that this broad definition applies and asserts that when used in Count XXI, which is the proposed inequitable conduct claim, “Applicants” is separately defined to refer only to the named inventors, which is a discrete group of six individuals. See [ECF No. 221-19 at 10–11; ECF No. 176-5 ¶ 246 (stating that “[d]uring prosecution, each of the named inventors self-identified as and was referred to as ‘Applicant’ or ‘Applicants’ of the ’045 patent.”)]. Lilly fails to mention, however, that its proffered definition of “Applicants” does not appear until more than fifty paragraphs into Count XXI and after the term “Applicants” had been used more than twenty times within the counterclaim. [ECF No. 176-5 ¶¶ 187–245]. Thus, its argument that any reference to “Applicants” should be interpreted to refer only to the named inventors strains credulity. Further, throughout Count XXI, Lilly separately uses the term “named inventors,” which shows that when it wanted to refer to this defined group, it used “named inventors,” not “Applicants.” E.g., [id. ¶¶ 267–68]. Accordingly, because the allegations that refer generally to “Applicants” encompass many potential individuals and entities, they do not meet the specificity requirements of Rule 9. See Exergen Corp., 575 F.3d at 1329 (finding that allegations that generally refer to “Exergen, its agents, and/or attorneys” failed to “identify the ‘who’ of the material omissions and misrepresentation”).

With the references to “Applicants” stripped away, the Court must determine whether the remaining factual allegations contain “the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” Exergen, 575 F.3d at 1327.

In its briefing, Lilly largely focuses on three specific individuals who made misrepresentations to the PTO: [REDACTED] and Dr. Giering.

For [REDACTED] Lilly alleges that these two inventors knew about [REDACTED], but did not disclose them. [ECF No. 176-5 ¶¶ 215 [REDACTED]; 219 [REDACTED] were not disclosed in the November 2006 PCT Application, which led to the patents-in-suit.”); 220 (“At least [REDACTED] were involved in drafting the November 2006 PCT Application . . . containing claims broadly reciting anti-CGRP antagonist antibodies, not limited by structure or even epitope.”); 285, 287, 294 (alleging that the named inventors, which included [REDACTED] knew about the [REDACTED] and that [REDACTED] were not disclosed)]. Lilly also alleges that [REDACTED]

[REDACTED] For Dr. Giering, the proposed amended answer specifically alleges that in June 2013 he submitted an application to the PTO during prosecution of the ‘045 patent that stated that “any antibody that effectively binds CGRP may reasonably be expected to have the claimed effect.” [Id. ¶ 260]. The factual allegations relating to these three individuals are all specific enough to satisfy the heightened pleading standard.

Also, the three categories of withheld information [REDACTED] [REDACTED] [REDACTED] were plainly material. “[T]he materiality required to establish inequitable conduct is but-for materiality.” Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed. Cir. 2011). Information is material if “there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent,” Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007) (citing 37 C.F.R. § 1.56(a) (1991)), or “it falls within the standards set forth in PTO Rule 56” which explains that information is material if “it is not cumulative to information already of record or being made of record in the application, and . . . [i]t refutes, or is inconsistent with, a position the applicant takes in: (i) [o]pposing an argument of unpatentability relied on by the [PTO], or (ii) [a]sserting an argument of patentability.” Signify N. Am. Corp. v. Reggiani Lighting USA, Inc., No. 18-cv-11098, 2020 WL 1331919, at *5 (S.D.N.Y. Mar. 23, 2020) (quoting Nycomed U.S. Inc. v. Glenmark Generics Ltd., No. 08-cv-05023, 2010 WL 1257803, at *14 (E.D.N.Y. Mar. 26, 2010)). The 2006 PCT Application claims “[a] method for preventing or treating at least one vasomotor symptom in an individual, comprising administering to the individual an effective amount of an anti-CGRP antagonist antibody.” [ECF No. 176-6 ¶ 240]. Evidence that [REDACTED] [REDACTED] [REDACTED] directly cuts against the recited claim relating to anti-CGRP antibodies. Thus, if this information had been disclosed to the PTO, a reasonable examiner would have considered it important when deciding whether to issue the patent. Likewise, Lilly alleges that Dr. Giering’s June 2013 statement was made in response to criticism from the PTO and was ultimately the reason that the ‘045 patent issued. [ECF No. 176-6

¶¶ 260–63]. This supports the inference that a reasonable examiner would have found it important to know if the June 2013 statement were true or false.

Finally, the Court finds that the allegations in the proposed amended answer, when construed in Lilly’s favor, support the reasonable inference that [REDACTED] acted with specific intent and knew the materiality of the withheld information. Lilly alleges that [REDACTED]

[REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], [REDACTED]

[REDACTED] [REDACTED] [REDACTED]

[REDACTED] (8) during patent prosecution [REDACTED]

[REDACTED] signed declarations stating that they “reviewed and understand the contents . . . including the claims” of the 2006 PCT Application and acknowledged their duty to disclose to the PTO “all information known . . . to be material to patentability[,]” [*id.* ¶¶ 246–477]. Thus, considered together, the allegations suggest that [REDACTED] understood the significance of an antibody’s structure (i.e., ability to bind to different CGRP regions), were aware of the withheld information, had a role in drafting the 2006 PCT Application, and knew about their duty to disclose the material information, but chose not to do so. As a result, the Court may reasonably infer that they knew the withheld information was important and their intent was to deceive the PTO by not disclosing it. Teva argues that many inferences can be drawn from the

facts other than an intent to deceive. [ECF No. 207-1 at 20–23]. Although Teva’s theory may prevail at a later stage, Lilly is not required to prove its case at the pleading stage. See Exergen Corp. 575 F.3d at 1329 n.5 (“In contrast to the pleading stage, to prevail on the merits, the accused infringer must prove both materiality and intent by clear and convincing evidence.”).

Lilly’s allegations regarding Dr. Giering, however, do not fare as well. The proposed amended answer contains no allegation that Dr. Giering knew of [REDACTED] when he made the June 2013 statement, or that he understood the importance of [REDACTED]. Accordingly, the Court cannot reasonably infer that he even knew that his statement was false, let alone that it was material or meant to deceive. Thus, any inequitable conduct on the part of Dr. Giering is inadequately pled.

In sum, Lilly’s motion to amend its answer is GRANTED, except to the extent that it premises its inequitable conduct claim on Dr. Giering’s June 2013 statement or makes allegations generally about the “Applicants.”

IV. CONCLUSION

Accordingly, for the reasons set forth above, Teva’s motion for sanctions, [ECF No. 143], and Lilly’s motion to exclude, [ECF No. 181], are DENIED and Lilly’s motion to amend its answer, [ECF No. 175], is GRANTED, except to the extent that its inequitable conduct claim relies on Dr. Giering’s June 2013 statement to the PTO or makes allegations generally about the “Applicants.” Dr. Hale is ORDERED not to disclose any of Lilly’s confidential information or work product to Teva.

SO ORDERED.

December 20, 2021

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE