

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

ALLERGAN, INC., ALLERGAN
PHARMACEUTICALS IRELAND
UNLIMITED COMPANY, and
ALLERGAN USA, INC.,

Plaintiffs,

v.

REVANCE THERAPEUTICS, INC. and
AJINOMOTO ALTHEA, INC. d/b/a
AJINOMOTO BIO-PHARMA SERVICES,

Defendants.

Civil Action No. 21-1411-RGA

MEMORANDUM ORDER

Before me is Plaintiffs’ Motion for Leave to Amend Complaint. (D.I. 294). I have considered the parties’ briefing. (D.I. 295, 304, 308).

I. BACKGROUND

Plaintiffs filed the present action on October 1, 2021, alleging that Defendants infringed U.S. Patent No. 7,354,740 (“the ’740 patent”), U.S. Patent No. 8,409,828 (“the ’828 patent”), and seven other patents (collectively, “the Asserted Patents”). (D.I. 1). The Asserted Patents are directed towards purifying botulinum toxins, which allows them to be used in botulinum injectable products such as Plaintiffs’ BOTOX product. (D.I. 79 ¶¶ 14–16).

Plaintiffs have already amended their complaint twice, with the Second Amended Complaint (the “SAC”) having been filed on December 30, 2022. (D.I. 79). Of relevance to the present motion, the SAC cites to Defendants’ U.S. Patent No. 9,469,849 (“the ’849 patent”) as part of the discussion of Defendants’ manufacturing process for its botulinum injectable product.

(D.I. 79 ¶¶ 69–72). Dr. Curtis Ruegg, Defendant Revance Therapeutic’s former Executive Vice President for Research and Development, is credited as the sole inventor of the ’849 patent. (*Id.* ¶¶ 78–79). Plaintiffs now seeks to amend its complaint again, this time to add allegations of willful infringement claims of the ’740 and ’828 patents. (D.I. 294; *see* D.I. 294-1, Ex. A).

On September 23, 2022, Allergan served document requests and an interrogatory (“Interrogatory No. 3”) relating to Defendants’ knowledge and awareness of the Asserted Patents. (D.I. 295-1, Ex. 2 at 11; *id.*, Ex. 3 at 4). Defendants’ October 24, 2022 response to Plaintiffs’ discovery request objected to Interrogatory No. 3 on the basis that it was “not relevant to any claim or defense in this case . . . at least for the reason that Plaintiffs have not alleged willful infringement.” (D.I. 304-1, Ex. A at 13). Defendants’ response concluded, “Defendants do not intend to supply a response to this Interrogatory as currently drafted in view of the above-stated objections.” (*Id.*).

On November 18, 2022, Plaintiffs’ counsel wrote a letter to Defendants’ counsel asserting that Interrogatory No. 3 “concerns relevant information in this case, such as infringement and damages issues” and asking Defendants to “provide a supplemental response to this interrogatory without delay.” (*Id.*, Ex. B at 4). The parties met and conferred on January 12, 2023. (*See id.*, Ex. F). Defendants’ January 25, 2023 letter memorialized the meeting, stating, “As Allergan conceded during the parties’ meet and confer, willfulness and induced infringement are not at issue in this case. Thus, the information requested in Interrogatory No. 3 . . . [is] not relevant to any parties’ claims or defenses.” (*Id.*, Ex. C at 3).

On February 23, 2023, Defendants sent another letter reiterating their understanding of Interrogatory No. 3. (*Id.*, Ex. D at 3 (“Requests . . . directed to Defendants’ knowledge of the

Asserted Patents . . . are not relevant.”)). On February 28, 2023, Defendants sent an email to Plaintiffs that stated:

In your January 27, 2023 letter, Allergan states that it has not “conceded . . . willfulness and induced infringement are not at issue in this case.”

. . . .
When the parties met and conferred on January 12, 2023, . . . Allergan explicitly acknowledged that willful and indirect infringement are not part of this case. When Defendants memorialized this acknowledgement in their January 17, 2023 email, Allergan did not specifically deny these concessions. Instead, Allergan merely disagreed that these Requests “are not relevant to claims or defenses in this case.” Importantly, Allergan never affirmatively stated that it believed willfulness and indirect infringement were part of this case, or otherwise disagreed with Defendants’ statement that willfulness and indirect infringement are not part of this case.

Now, Allergan appears to walk back these positions. . . . Allergan’s shifting positions are not productive. If Allergan believes it has pled a claim of willful or indirect infringement, please direct us to where it believes such claims were made and to any allegations Allergan believes support such claims, so that Defendants may consider them.

(*Id.*, Ex. F) (citations omitted). Plaintiffs did not respond to this email. (D.I. 304 at 5).

Roughly six months later, on August 25, 2023, Plaintiffs served a deposition subpoena on Dr. Ruegg. (D.I. 207). On August 31, 2023, Plaintiffs informed Defendants that they would be moving to compel supplementation of Defendants’ Interrogatory No. 3 response. (D.I. 304-1, Ex. G at 4). Plaintiffs’ letter indicated the basis for its motion was that “Defendants’ position that Plaintiffs have not alleged induced infringement . . . is entirely baseless” and that “Defendants have never disputed that Plaintiffs have alleged contributory infringement. (*Id.* at 4 & n. 1). Plaintiffs amended its infringement contentions on September 19, 2023 to include contributory infringement allegations. (D.I. 304 at 5; *see* D.I. 304-1, Ex. H). Defendants agreed to supplement its Interrogatory No. 3 response, purportedly because they agreed that knowledge of the patents was a relevant inquiry for contributory infringement. (D.I. 304 at 5). This supplemental response was served on October 4, 2023. (D.I. 304-1, Ex. J).

Plaintiffs' counsel deposed Dr. Ruegg on October 6, 2023. (*See* D.I. 295-1, Ex. 6). On November 3, 2023, Defendants produced five documents from Dr. Ruegg's custodial files: copies of the '740 patent and the '828 patent (D.I. 295-1, Ex. 8; D.I. 295-2, Ex. 9), a copy of a publication of an earlier patent application leading to those patents (D.I. 295-2, Ex. 10), and *curriculum vitae* for two of the inventors of the '740 and '828 patents (D.I. 295-1, Ex. 11–12). Fact discovery closed on November 3, 2023. (D.I. 237). Defendants produced the underlying metadata associated with these documents on November 15, 2023. (D.I. 295 at 5).

On November 22, 2023, Plaintiffs informed Defendants that they intended to request leave to amend its complaint. (D.I. 304-2, Ex. K). Plaintiffs subsequently filed the present motion on January 19, 2024. (D.I. 294). The deadline for filing motions to amend pleadings was February 2, 2023. (D.I. 54 ¶ 2).

II. LEGAL STANDARD

Federal Rule of Civil Procedure 15(a)(2) states that, apart from amendments as a matter of course, “a party may amend its pleading only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). “The court should freely give leave when justice so requires.” *Id.* The Third Circuit has construed Rule 15, instructing that “absent undue or substantial prejudice, an amendment should be allowed under Rule 15(a) unless ‘denial [can] be grounded in bad faith or dilatory motive, truly undue or unexplained delay, repeated failure to cure deficiency by amendments previously allowed or futility of amendment.’” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Lundy v. Adamar of New Jersey, Inc.*, 34 F.3d 1173, 1196 (3d Cir. 1994)) (emphasis omitted).

Federal Rule of Civil Procedure 16(b) also applies when, as here, a party moves to amend past the date set by the scheduling order. *E. Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330,

340 (3d Cir. 2000); *Media Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at *1 & n.2 (D. Del. Nov. 14, 2016). Rule 16(b)(4) 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.” *Media Pharm.*, 2016 WL 6693113, at *1. “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).

III. ANALYSIS

Defendants argue that Plaintiffs cannot show good cause because Plaintiffs did not diligently pursue the discovery on which their proposed amendment rests. (D.I. 304 at 11). Defendants note that a total of six-and-a-half months elapsed between the amended pleadings deadline and the Plaintiffs’ deposition subpoena to Dr. Ruegg. (*Id.* at 12).

Plaintiffs argue that Defendants “misleadingly frame[] the timeline of the parties’ interactions,” but Plaintiffs do not assert any material differences to Defendants’ version of events. (D.I. 308 at 4). The record demonstrates that, between October 2022 and February 2023, Defendants repeatedly made clear their understanding that willful infringement and induced infringement were not at issue in this case and, therefore, they did not intend to supplement their Interrogatory No. 3 response or produce evidence related to knowledge of the Asserted Patents. Plaintiffs did not pursue any courses of action to further the production of relevant discovery. For example, Plaintiff did not raise any discovery disputes resulting from Defendants’ clear indication that they would not produce evidence related to willfulness. Nor did Plaintiffs respond to Defendants’ February 28, 2023 email which sought clarification on Plaintiffs’ posture in light of perceived disparities between the positions Plaintiffs expressed at the January 12,

2024 meet and confer and in their January 27, 2024 email.¹ Plaintiffs instead waited six months before taking their next step to advance willfulness-related discovery by serving a deposition subpoena of Dr. Ruegg.²

Plaintiffs provide no explanation for their failure to engage in diligent discovery efforts between February 2023 and August 2023. Plaintiffs instead attempt to center the diligence inquiry on the period starting in August 2023, when they began their discovery efforts that led to the acquisition of “new” information related to willfulness. (D.I. 295 at 7–9; D.I. 308 at 2–6). Even accepting Plaintiffs’ diligence from August 2023 onwards, Plaintiffs’ later diligence does not excuse half a year of inaction.

In sum, Plaintiffs fail to establish good cause where, instead of diligently pursuing discovery, they idled for six months before launching earnest efforts to obtain the relevant evidence. I therefore decline to grant Plaintiffs leave to amend their complaint to add willful infringement claims.

I need not address Defendants’ remaining arguments.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs’ Motion for Leave to Amend Complaint (D.I. 294) is **DENIED**.

¹ Though the February 28, 2023 email came after the February 2, 2023 deadline, it was written as a response to Plaintiffs’ January 27, 2023 letter. (D.I. 304-1, Ex. F). Plaintiffs’ diligence argument would be more credible had Plaintiffs pursued timely action in response to this email.

² Plaintiffs’ August 31, 2023 letter suggests the basis for their seeking patent-related discovery was not related to willful infringement claims. (See D.I. 304-1, Ex. G at 4 & n. 1). I nevertheless assume the opposite for the purposes of this motion, as making that assumption does not affect my conclusion.

IT IS SO ORDERED.

Entered this 17th day of May, 2024


United States District Judge