IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC.,	)	**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY - FILED UNDER SEAL**
Defendants.	)	

LETTER BRIEF TO THE HONORABLE MITCHELL S. GOLDBERG REGARDING PLAINTIFFS' MOTION FOR LEAVE TO AMEND COMPLAINT

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
Emily S. DiBenedetto (No. 6779)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
edibenedetto@shawkeller.com
Attorneys for Plaintiffs

OF COUNSEL:
David I. Berl
Adam D. Harber
Thomas S. Fletcher
Jessica Palmer Ryen
Shaun P. Mahaffy
Jihad J. Komis
Anthony H. Sheh
Matthew W. Lachman
Philip N. Haunschild
Falicia Elenberg
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000
Attorneys for Plaintiff Genevant Sciences GmbH

Daralyn J. Durie
Adam R. Brausa
Eric C. Wiener
Annie A. Lee
Shaelyn K. Dawson
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-6080

Kira A. Davis
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017-3543
(213) 892-5200

David N. Tan
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, DC 20037
(202) 887-1500
Attorneys for Plaintiff Arbutus Biopharma Corporation

Dated: April 17, 2024

Dear Judge Goldberg:

Following the Court's February 27, 2024 Discovery Order, D.I. 229, Moderna finally—after a year of repeated requests by Plaintiffs—supplemented its response to Interrogatory No. 11 on March 12 to provide crucial details needed to identify infringing batches of the Accused Product. That supplement revealed new evidence that Moderna is infringing Plaintiffs' asserted patents not just under the statutory provisions asserted in the Complaint, but also under an additional provision in U.S. patent law. In particular, Moderna's supplemental response incorporates a newly-produced "export of the part number genealogy" for the Accused Product showing that Moderna supplied its foreign manufacturing sites with *U.S.-manufactured components* of the Accused Product (the mRNA and [redacted]). *See* Exs. A; B at 2–3. This constitutes infringement under 35 U.S.C. § 271(f). While the witnesses and major factual issues in the case are unchanged by this new theory, it could significantly increase the number of batches at issue, and thus the amount of damages, including by providing another basis for those batches where the parties' dispute whether they qualify as U.S. sales. Plaintiffs thus respectfully move for leave to amend their Complaint.

"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." *WebXchange Inc. v. Dell Inc.*, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010). Under Federal Rule 15(a)(2), leave should be granted absent undue delay, bad faith, dilatory motives, or futility. *Id.* When leave is sought after the deadline in a scheduling order, good cause is required under Federal Rule 16(b)(4), meaning that the movant must show that "despite diligence, the proposed claims could not have been reasonably sought in a timely manner." *Roquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at *4 (D. Del. May 21, 2009). That standard is easily met here—the Court should not reward Moderna's failure to meet its discovery obligations.

Plaintiffs have repeatedly sought discovery regarding the locations of manufacture for components of the Accused Product. After Moderna disclosed the use of multiple intermediate components in the Accused Product in early in 2023, Plaintiffs sought discovery into those components, including their manufacturing location. On March 16, 2023, Plaintiffs served an Interrogatory seeking detailed information about Moderna's manufacturing process, including asking Moderna to identify each of the intermediates (such as the mRNA and [redacted]) in its product and "where that manufacturing occurred." Ex. C. In short, Plaintiffs sought a "genealogy" for each batch of the finished vaccine—information regarding the [redacted]—so Plaintiffs could identify the infringing batches.

Moderna refused to provide this information. Specifically, Moderna objected to providing information about "batches and/or lots of these starting materials and/or intermediates." Ex. D, Response to Interrogatory No. 11 at 4. Plaintiffs immediately asked Moderna to supplement its response. On April 18, 2023, Plaintiffs informed Moderna that it had not provided Plaintiffs with "even a basic accounting of the infringing units that Moderna has manufactured, distributed, and sold to date." Ex. E. Plaintiffs specifically called out the relevance of "intermediate products and their components," explaining that "Moderna's restriction of its agreed-upon scope to the final drug product and mRNA-1273 Lipid Nanoparticle is improper." Ex. F, April 28, 2023 Genevant Letter; Ex. G, June 29, 2023 Genevant Letter.

Over the span of 9 months—from April to December 2023—Moderna strung Plaintiffs along with piecemeal information, without disclosing the location of manufacture for the components that went into the batches that Moderna contended were manufactured abroad. In July, Moderna said it hoped to produce the requested genealogy information—the key evidence supporting this amendment—that same month. Ex. H, July 12, 2023 Moderna Letter (hoping "to collect" and provide "batch disposition and genealogy" in July, but would provide an update "in due course"). But Moderna did not produce this genealogy information in July or even in the following 4 months, despite Plaintiffs' continued entreaties. *E.g.*, Ex. I, Nov. 7, 2023 Genevant Email.

Not until December 15, 2023, did Moderna serve the promised supplement. In doing so, Moderna *again* omitted disclosure of the use of U.S.-manufactured components for batches finished overseas. Instead, it only provided genealogies for batches of the finished vaccine manufactured at the locations in the U.S. *See* Ex. J, First Supp. Resp. to Interrogatory No. 11 at 6. Plaintiffs filed a motion to compel that same day, December 15, 2023, seeking samples of Moderna's Accused Product, together with the information necessary to select the samples. *See* D.I. 161.

On February 27, the Court ordered Moderna to "produce to Plaintiffs all remaining information about batch/lot numbers." D.I. 229. Only on March 8, 2024, did Moderna finally produce the genealogy information cited in its Interrogatory supplement a few days later, which showed that supposedly foreign-made batches in fact were made with components manufactured in the United States. Ex. A. Plaintiffs wrote to Moderna shortly thereafter, on March 22, 2024, Ex. B, Genevant Letter, and met and conferred on seeking leave to amend on April 10. Moderna refused to consent, necessitating a contested motion.

The newly-produced evidence is good cause to amend under Rule 16. There is good cause to amend after the deadline in the scheduling order where a plaintiff "only discovered the evidence motivating its motion for leave to amend after the . . . deadline for moving to amend had passed." *Int'l Constr. Prod. LLC v. Caterpillar Inc.*, 2018 WL 4611216 at *2 (D. Del. Sept. 26, 2018). Here, Plaintiffs only discovered that evidence when Moderna finally supplemented its interrogatory response on March 12, 2024—per a Court order—pointing Plaintiffs to part number genealogy information produced a few days earlier. Until Moderna answered Plaintiffs' question about where vaccine components were manufactured, Plaintiffs were left with Moderna's public statements suggesting that it used "a dedicated supply chain to support Europe and countries other than the United States" in Switzerland and Spain. Ex. K, Press Release (Nov. 25, 2020).

Because of Moderna's intransigence, Plaintiffs did not learn the truth about Moderna's supply chain until well after the deadline for amendment, and this motion promptly followed. During the parties' meet and confer regarding this motion, Moderna has never asserted that Plaintiffs could have learned of the relevant facts earlier. And even if it had, a Plaintiff is not judged by when it hypothetically knew enough to amend, but instead is entitled to first obtain key documents or other corroborating discovery. *Targus Int'l LLC v. Victorinox Swiss Army, Inc.*, 2021 WL 2291978 at *3 (D. Del. June 4, 2021); *Caterpillar Inc.*, 2018 WL 4611216 at *2–3.

Plaintiffs acted diligently to obtain the information needed for this amendment and to seek leave once it was obtained. Repeatedly, for more than a year, Plaintiffs sought information about the manufacturing location for the components of Moderna's vaccine. Moderna only provided that

information in the last several weeks, and only in response to a Court order for it to do so. Ex. L, Moderna Email (Mar 12, 2024) (indicating that the discovery at issue was provided to "comply with Paragraph 1(a) of the Court's Order dated February 27, 2024").

If Plaintiffs cannot amend their complaint, Moderna would unfairly benefit from its earlier refusal to disclose that key components of supposedly foreign batches were made in the U.S—the significance of which Moderna undoubtedly understood. Moderna should not be permitted to permanently avoid the consequences of supplying components from the U.S. on the basis of its own discovery conduct. Plaintiffs' diligence is clear: they sought discovery on this issue from the start, repeatedly asked Moderna for more complete responses, and ultimately needed the Court's assistance. As in similar cases, Moderna "really cannot win an argument that Plaintiff should have been more aggressive in getting Defendant[] to meet their obligations." *Caterpillar*, 2018 WL 4611216 at *3 (holding that Defendants' delay did not show Plaintiff's lack of diligence).

Plaintiffs also acted diligently "once [they] became aware of the issues underlying [their] proposed amendments," *Compagnie des Grands Hotels d'Afrique SA v. Starwood Cap. Grp. Glob. I LLC*, 2021 WL 6883231 at *5 (D. Del. Feb. 10, 2021), writing Moderna nine days after receiving the supplement, conferring a week after receiving Moderna's response, and filing this motion five days later. Just over a month passed between Moderna's delinquent disclosure and this motion. *See Home Semiconductor Corp. v. Samsung Elecs. Co.*, 2019 WL 2135858 at *5 (D. Del. May 16, 2019) (filing three months after receiving information was diligent).

Granting leave would not prejudice Moderna.[1] While prejudice to the non-moving party is the "touchstone" of the Rule 15 inquiry, *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006), additional expense or discovery does not establish prejudice. Rather, Moderna must show "that its ability to present its case would be seriously impaired were amendment allowed." *Dole v. Arco Chemical Co*., 921 F.2d 484, 488 (3d Cir. 1990). There is no possible prejudice here because the amendment asserts a new legal theory based on virtually the same facts. *Cf. Home Semiconductor*, 2019 WL 2135858 at *5 (no prejudice from adding allegations under § 271(g) because infringement allegations remained the same). Plaintiffs' amendment would not change the asserted patents, the underlying infringement analysis, the damages theories, the relevant fact witnesses, or the case schedule. It would simply expand the number of doses for which Plaintiffs can obtain damages. The extent of the additional discovery needed is essentially lines on a spreadsheet reflecting the batches for which components were manufactured in the U.S. and targeted financial and technical information relating to those batches.

Prejudice is particularly absent here because all of the new information is already in Moderna's possession. *See Dasso Int'l, Inc. v. MOSO N. Am., Inc.*, 2020 WL 6287673 at *4 (D. Del. Oct. 27, 2020) (minimal prejudice where information already in party's control). The parties also still have more than a month left of fact discovery—indeed, neither party has yet begun taking depositions. *Targus Int'l*, 2021 WL 2291978 at *3 (no prejudice where a month of discovery remained). Moderna should not be rewarded for its stonewalling, and Plaintiffs respectfully request leave to file the attached Amended Complaint, Exs. M (redline); N (clean).

[1] There is no undue delay under Rule 15 where diligence is found under Rule 16. *See Home Semiconductor*, 2019 WL 2135858 at *5.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.