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.,	)	
Defendants.	)	

LETTER TO THE HONORABLE MITCHELL S. GOLDBERG FROM NATHAN R. HOESCHEN REGARDING DISCOVERY DISPUTE

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BY CM/ECF
The Honorable Mitchell S. Goldberg
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Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.* C.A. No. 22-252-MSG

Dear Judge Goldberg:

Plaintiffs move for the production of three limited, relevant categories of documents. Plaintiffs first seek a narrow set of regulatory documents for products that use LNPs with the lipid molar ratios in Plaintiffs' asserted patent claims—specifically, the chemistry, manufacturing, and controls sections (typically contained in Module 3) of Moderna's "Investigational New Drug" applications ("INDs") and related correspondence with the FDA. These documents, which are relevant to non-obviousness, willful infringement, and damages, can be produced from a centralized repository with minimal burden. Second, Plaintiffs seek documents concerning the marketing, negotiation, and contracting for batches of Moderna's COVID-19 vaccine that Moderna unilaterally declares are "not accused of infringement" because they were allegedly ***manufactured*** and ***used*** abroad. However, such batches, which are accused of infringement, could have been ***sold*** in the U.S. under black-letter law, and are thus subject to damages in this action. Moderna cannot prevent discovery about the locus of sale for these batches based on its untested say-so. Third, Plaintiffs seek minutes from meetings of, and materials provided to, Moderna's Board of Directors discussing the accused product. This is a narrow category of documents that are squarely relevant to damages, and Moderna has not asserted any undue burden.

INDs (RFPs 163–67, Ex. 1 at 9–10). Despite criticizing Plaintiffs' LNP technology both publicly and in this case, Moderna repeatedly sought FDA approval to perform human testing using LNPs within the scope of Plaintiffs' asserted patent claims. Moderna publicly has admitted to performing such studies using LNPs within Plaintiffs' claimed ratios, Ex. 2 at 1322–24; Ex. 3 at 3327–28. The INDs seeking approval to perform these human studies contain detailed, non-public statements that discuss the patented technology, report on studies with the technology, and provide scientific justifications for use of Plaintiffs' claimed lipid molar ratios and components.

There is no genuine dispute that Moderna's INDs are relevant. [redacted] Exs. 4, 5; Ex. 6 at 28–29. [redacted] Ex. 7 at *767. And Moderna repeatedly has demanded that Plaintiffs also produce INDs sponsored by Plaintiffs' predecessors. While Plaintiffs agreed to produce such documents, Ex. 8 at 1, Moderna has steadfastly refused to produce the requested IND excerpts, despite admitting that it maintains them in a centralized repository, minimizing any production burden on Moderna.

Any such minimal burden is vastly outweighed by the documents' substantial relevance. For example, by reflecting Moderna's widespread copying of the patented inventions, Moderna's

INDs provide "compelling evidence" nullifying its obviousness defenses, to the extent Moderna is not estopped from raising them in light of its failed IPRs. *Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000). Moderna's INDs are also relevant to willful infringement by demonstrating its knowledge of, and history with, the patents and patented technology. *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1245 (Fed. Cir. 2017). Even divorced from these legal theories, Moderna's INDs likely contain statements directly commenting on the technology at issue in this case, and are plainly relevant for that reason as well.

Moderna offers no valid reason the requested IND sections should not be produced. First, Moderna asserts that certain INDs (from 2017) are irrelevant to copying and willfulness because Moderna's work was conducted pursuant to an unauthorized sublicense from Acuitas, D.I. 1 ¶¶ 32–34, or based on publicly available information. Setting aside that this argument does not address the full scope of non-public INDs that Plaintiffs seek, Moderna's attorney argument does not render its INDs non-discoverable. Nor does the fact that certain IND studies may have been conducted pursuant to a license change their relevance to willful infringement here, which concerns activities beyond the scope of the license. *Georgetown Rail*, 867 F.3d at 1245. And none of this addresses the fact that the requested documents contain Moderna's indisputably relevant statements regarding the patented technology.

Moderna also objects that the INDs concern non-accused products. But the requested INDs include information about [redacted] Exs. 2–6. Regardless, there is no rule limiting discovery to the accused product only. *See, e.g.*, *Eli Lilly & Co. v. Wockhardt Ltd.*, 2010 WL 2605855, at *5 (S.D. Ind. June 22, 2010) (compelling production of IND for another formulation). "[C]ourts have allowed discovery to include non-accused products where a party either demonstrates the relevance of the non-accused products to the allegations and or their reasonable similarity to the accused product," as Plaintiffs have done here, and "Delaware federal district courts . . . have concluded that discovery into non-accused products, particularly prior to the filing of final contentions, is permissible as long as it is narrowly tailored." *LKQ Corp. v. Kia Motors Am., Inc.*, 2023 WL 3455315, at *3 (N.D. Ill. May 15, 2023); *Invensas Corp. v. Renesas Elecs. Corp.*, 287 F.R.D. 273, 283 (D. Del. 2012); *Elm 3DS Innovations, LLC v. Samsung Elecs. Co., Ltd.*, 2015 WL 13902870, at *1–2 (D. Del. June 30, 2015). Moderna's INDs for products using Plaintiffs' lipid ratios are precisely the sort of "narrowly tailored," highly relevant discovery that poses minimal burden, and should be compelled.

Sales Discovery (RFPs 60, 64, 69, 74, 75, 81, 83, Ex. 9 at 14–18; Interrog. 11, Ex. 10). Moderna also refuses to produce discovery concerning sales of the batches that it unilaterally deems non-infringing under 35 U.S.C. § 271(a) because they were not manufactured or used in the U.S. Ex. 11 at 1. Moderna disregards Plaintiffs' allegations that Moderna's ***sales*** of these batches occurred in the U.S., *e.g.*, D.I. 1 ¶¶ 50–54, 70, and defies binding precedent stating that such U.S. sales are infringing acts. *E.g.*, *Caltech v. Broadcom Ltd.*, 25 F.4th 976, 993 (Fed. Cir. 2022); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1310 (Fed. Cir. 2015). Sales "for products manufactured, delivered, and used ***entirely abroad***," may "be found to have occurred in the United States"—and thus infringing under § 271(a)—"where a substantial level of sales activity occur[ed]" in the U.S. Ex. 12 at Appx184, *aff'd in relevant part Caltech*, 25 F.4th at 992. And products "not made or used in, or imported into, the United States" may infringe if there is a "domestic location of sale." *CMU*, 807 F.3d at 1310. Determining where a sale occurred is a fact-specific inquiry, in which courts have considered (1) where a contract or sale was negotiated; (2) where purchase orders and payments issue or are received; (4) where a contract was executed; (5)

where contingent actions under a contract occur; (6) where specific orders are negotiated or finalized; (7) where marketing activities occur or are directed; and/or (8) where testing or design work underlying the sale occurred. *See, e.g.*, *Caltech*, 25 F.4th at 976; *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 831 F.3d 1369, 1378 (Fed. Cir. 2016); *CMU*, 807 F.3d at 1308; Ex. 13.

Moderna ignores this precedent, and refuses discovery, by baldly declaring its sales occurred abroad. Ex. 14 at 1. Moderna improperly confuses its unilateral view of the merits of infringement with discoverability. Plaintiffs are not obligated to accept Moderna's untested assertions, but are "entitled to discover the extent to which [Moderna] has engaged in foreign sales activities" to determine if sales of products made and used abroad in fact "occurred within the U.S." *McGinley v. Luv N'Care, Ltd.*, 2018 WL 9814589, at *5 (W.D. La. Sept. 10, 2018). Plaintiffs are "not required to prove [their] case" for infringing sales "before being entitled to such discovery." *Apeldyn Corp. v. AU Optronics Corp.*, 2010 WL 11470585, at *1 (D. Del. Apr. 12, 2010) (compelling "worldwide sales data"); *Pos. Techs., Inc. v. Sony Elecs., Inc.*, 2013 WL 707914, at *6 (N.D. Cal. Feb. 26, 2013) ("It would be improper under Rule 26 to expect Plaintiff to show that the discovery it seeks is admissible when it has not yet obtained the discovery."). Moderna cannot dispute that significant sales activities occurred at its U.S. headquarters, key testing and design work occurred in the U.S., and employees executed contracts in the U.S. Moderna should be compelled to produce documents and information concerning the sales of its COVID-19 vaccine that it contends were for batches manufactured and used abroad, and not to limit discovery to batches manufactured or used in the U.S, as it has in response to each of Plaintiffs' requests.[1]

Board Materials (RFP 130, Ex. 1 at 2). Moderna refuses to produce minutes of meetings of, and materials provided to, its Board of Directors discussing the accused product. Moderna has acknowledged that this request "is narrowly circumscribed," Ex. 15 at 7, and has not disputed relevance. Nor could it. Such materials are directly relevant to damages, as planning and strategy around the accused product are evidence about the hypothetical negotiation. Indeed, Moderna's CEO testified before Congress that its Board made strategic sales decisions, including agreeing to give an unsolicited ***$2.9 billion*** discount to the U.S. Government. Ex. 16, 54:5-22, 83:9. Moderna also has not asserted burden, as such materials generally are centrally stored. Ex. 15 at 10.

Moderna's sole basis to resist production has been shifting counter-demands. Plaintiffs agreed to produce the same scope of Board materials requested from Moderna, plus more. Ex. 15 at 4. So Moderna demanded yet more: first that Plaintiffs produce their and their predecessors' board materials concerning not just the accused product, but effectively every LNP made in their two-decade-plus history. Then, Moderna demanded that Plaintiffs ***and*** non-party Roivant produce documents discussing lipid molar ratios and the asserted patents. Ex. 15 at 2. This conditioning is improper. *Genentech, Inc. v. Trustees of Univ. of Pa.*, 2011 WL 7074208, at *1 (N.D. Cal. June 10, 2011). The documents Plaintiffs seek are targeted and plainly relevant to damages. Courts routinely compel defendants in patent litigation to produce board materials regarding the accused product, and Plaintiffs respectfully request the Court follow suit here. *E.g.*, *Vasudevan Software, Inc. v. MicroStrategy Inc.*, 2013 WL 597655, at *1 (N.D. Cal. Feb. 15, 2013) (ordering production of board minutes); *Unilin Beheer B.V. v. NSL Trading Corp.*, 2015 WL 12698382, at *9 (C.D. Cal. Feb. 27, 2015) (ordering investigation into board minutes and other financial documents).

[1] Plaintiffs have also sought samples of such batches. D.I. 161.

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