IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

LETTER TO THE HONORABLE MITCHELL S. GOLDBERG REGARDING DISCOVERY DISPUTE

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Dear Judge Goldberg:

Plaintiffs return to the Court to obtain discovery regarding Moderna's U.S.-based sales of the Accused Product. Plaintiffs previously sought the Court's assistance in obtaining discovery regarding sales of the Accused Product that Moderna unilaterally—and improperly—characterized as "foreign sales" solely because the product was manufactured and delivered abroad. *See* D.I. 184. As the Federal Circuit has made clear, however, products "not made or used in, or imported into, the United States" may infringe if there is a "domestic location of sale." *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1310 (Fed. Cir. 2015); *Caltech v. Broadcom Ltd.*, 25 F.4th 976, 993 (Fed. Cir. 2022). Following argument, the Court directed Plaintiffs to: "propound to Defendant specific interrogatories about such sales that are narrowly-tailored to the factors enumerated in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 831 F.3d 1369 (Fed. Cir. 2016). After review of Defendant's responses, if Plaintiffs are able to demonstrate that a specific sale could be deemed a 'U.S. Sale,' they may renew their request for documents as to that sale." D.I. 229 ¶ 5. Plaintiffs have done precisely as the Court directed. Ex. 1. Following an extensive meet-and-confer process, Plaintiffs identified 32 contracts—with 16 counterparties—all executed in June 2021 or prior, for which Plaintiffs have established a basis to pursue further discovery into their status as U.S. Sales. Ex. 2 (5/9/2023 Letter) at 2. Plaintiffs have requested discrete categories of documents concerning this limited set of agreements. *Id.* at 3. Plaintiffs also identified certain contracts for which Moderna's interrogatory response does not provide sufficient detail.

Moderna continues its flat refusal to provide discovery. It contends, again, that Plaintiffs are not entitled to discovery because they have not proven that "substantial sales activity" occurred in the United States. Ex. 3 (5/23/24 Email from Moderna). Not only is that wrong—based on limited discovery provided to date, a majority of the Federal Circuit's factors for determining a U.S. locus of sale support such a finding—but it flips the discovery process on its head and flouts the Court's order. Plaintiffs need not ***prove*** at this stage that the sales at issue occurred in the United States. They need merely show that they ***could*** make such a finding. As set out below, there can be no question Plaintiffs meet this standard. Plaintiffs' requests as to the sales in question are narrow and more than proportional, given that as much as [redacted] in sales of the Accused Product are at issue. Unless Moderna is willing to stipulate that the sales at issue are U.S. sales, it cannot continue to withhold discovery in an effort to avoid this liability.

Discovery Suggests that the Sales at Issue are U.S. Sales. "[F]or products manufactured, delivered, and used entirely abroad" a "sale" may "be found to have occurred in the United States where a substantial level of sales activity occur[ed]" in the U.S. Ex. 4 (*CalTech v. Broadcom, Ltd.*, 2:16-cv-03714 (C.D. Cal. Jan 29, 2020), D.I. 213) at Appx184, *aff'd in relevant part Caltech*, 25 F.4th at 992. Determining where such "substantial activity" occurred for products manufactured and delivered abroad considers (1) where a contract or sale was negotiated; (2) where purchase orders and payments issue or are received; (3) where a contract was executed; (4) where contingent actions under a contract occur; (5) where specific orders are negotiated or finalized; (6) where marketing activities occur or are directed; and/or (7) where testing or design work underlying the sale occurred. *See, e.g.*, *Halo*, 831 F.3d at 1378; *CMU*, 807 F.3d at 1308; Ex. 5 at 12–16. Based on the limited discovery to date, each one of these factors favors Plaintiffs for the pre-June 2021 contracts for which Plaintiffs seek further discovery:

Factor	Current Evidence
(1) Location of Contract Negotiation (*Halo*, 831 F.3d at 1378)	[redacted]
(2) Where Purchase Orders were Received and Processed (*Halo*, 831 F.3d at 1378)	
(3) Location of Contract Execution (*Halo*, 831 F.3d at 1378)	
(4) Location in which Contingent Actions in Contract Occurred (*CMU*, 807 F.3d at 1311, 1308–09)	
(5) Location Where Specific Orders Were Negotiated and Finalized (*CMU*, 807 F.3d at 1308)	
(6) Location Where Marketing Activities were Directed (*Halo*, 831 F.3d at 1378)	
(7) Location of Design Work and Testing (*Halo*, 831 F.3d at 1378)	

Moderna may dispute the implication of this evidence at trial, but its disagreement is not a basis to resist discovery. *See Apeldyn Corp. v. AU Optronics Corp.*, 2010 WL 11470585, at *1 (D. Del. Apr. 12, 2010) (Plaintiffs "not required to prove [their] case before being entitled to such discovery."). Moderna's own cases cited previously confirm that "the question [] is not whether [Defendant] has some facts on its side that it can later use to argue the ultimate issue . . . [n]or is the question here whether [Plaintiff] can now definitively *prove* that these sales are U.S.-based sales." *Tessera, Inc. v. Broadcom Corp.*, No. CV 16-380-LPS-CJB, 2017 WL 4876215, at *3 (D. Del. Oct. 24, 2017) (cited in Ex. 3 at 1). Rather, "the question is whether [Plaintiff] has made a sufficient record to demonstrate relevance." *Id.* Nor does the "presumption against extraterritorial application of United States law" limit further discovery. *See* Ex. 5 at 18. The Federal Circuit already has rejected that precise argument, concluding that "the presumption against extraterritorial application is [] inapplicable" to the determination of whether specific transactions "were domestic or extraterritorial in nature." *Caltech*, 25 F.4th at 992.

The Requested Discovery Is Limited and Proportional. Plaintiffs seek two categories of materials. First, after receiving Moderna's Court-ordered interrogatory response, Plaintiffs made every effort to identify a targeted set of documents for Moderna's pre-June 2021 sales that occurred before [redacted]. To that end, for each of the 32 contracts at issue, to the extent Moderna continues to dispute that the U.S. is a situs of sale, Plaintiffs requested 30(b)(6) corporate testimony regarding these sales, together with the following documents:

- ***Copies of the agreements***: Copies of Moderna's contracts are relevant to establish the price for which Moderna sold the Accused Product, the timing of Moderna's sales, and to assess other contractual provisions establishing a U.S. situs of sale, such as the location of the law applied under the agreement, parent guaranties with Moderna's U.S. affiliate, and may include U.S. locations for notice and/or payment.
- ***Negotiation communications***: Moderna's discussions concerning the negotiation of each agreement are relevant to assessing the location from which Moderna's negotiations were performed, unless stipulated.
- ***Sales orders***: Moderna's sales orders are relevant to confirm the location in which they were processed together with the dates of specific sales.
- ***Financial, distribution, and genealogical information about the doses sold pursuant to those agreements (to the extent not already produced)***: Plaintiffs are entitled to the information relevant to assess infringement and damages on a lot-by-lot basis (as Moderna contests) to prove their case for each infringing sale.
- ***Identification of new "part numbers" placed at issue*** for doses sold under these contracts so that Moderna may produce samples under the existing sample production protocol, D.I. 225.

Each of these limited categories relates directly to the *Halo* factors and Plaintiffs' burden to prove infringement for the product sales at issue.

Second, for the post-2021 contracts identified in Moderna's interrogatory response, Plaintiffs request that the Court Order Moderna to supplement its response to provide information broken down by specific contract, so Plaintiffs can assess concretely whether specific sales are U.S. sales, and whether further targeted discovery is warranted as to specific contracts. As it stands, Moderna has lumped together its responses in a way that prevents the necessary contract-by-contract analysis. For example, Moderna lists all U.S. and foreign sales employees without identifying which employees worked on which contracts, or their respective roles. Ex. 5 at 21.

Moderna contends that providing the above discovery would be burdensome, given the notice and confidentiality obligations Moderna owes to its counterparties. Ex. 3 at 1; Ex. 6 at 17–18. But the burden that Moderna has previously asserted—providing notices of disclosures for more than 100 agreements—no longer applies to Plaintiffs' current request for contracts with just 16 counterparties—a total of 32 agreements. Ex. 2 at 3. Moreover, Moderna has already selectively produced at least six of these agreements, thereby requiring additional notice obligations to just 10 counterparties. *See* Exs. 7–12. Moderna, moreover, may avoid some of the additional burden of producing its negotiation communications if it is willing to stipulate that the contracts at issue were negotiated entirely from the U.S. Absent such a stipulation, the documents Plaintiffs request are plainly proportional given Moderna's position that as much as [redacted] in sales may be in dispute. Ex. 15 (3/15/24 8th Supp R&Os) at 97. Any additional discovery would not affect the case schedule. If Moderna produces the requested information promptly before expert reports, it can be incorporated on the current schedule or handled with prompt, targeted supplements.

Plaintiffs respectfully request that Moderna be ordered to provide the requested discovery within two weeks of the Court's order.

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