IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, | ) | **REDACTED** |
| 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**

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**BY CM/ECF**
The Honorable Mitchell S. Goldberg
U.S. District Court for the Eastern District of Pennsylvania
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**FILED UNDER SEAL**

**HIGHLY CONFIDENTIAL**
**OUTSIDE COUNSEL'S EYES ONLY**

Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.* C.A. No. 22-252-MSG

Dear Judge Goldberg:

Plaintiffs move to compel Defendant Moderna to produce the most basic discovery one can request in a patent case: samples of the accused product. Moderna has agreed to produce samples from only a minority of the accused product batches—about 480 expired batches plus a handful of other batches out of approximately 2000 (if not more) at issue.[1] But Moderna refuses to produce samples of other batches, [redacted], all while maintaining the right to contest infringement of those unproduced batches. This position is untenable. Moderna's accused product varies batch-by-batch. Plaintiffs thus seek samples from the remaining batches (or a sufficient sampling, if the prejudice of Moderna's withholding of relevant discovery is mitigated by precluding it from disputing infringement of withheld batches). Plaintiffs also move to compel [redacted], along with associated data.

**Drug Product Samples (RFP No. 97).** A central issue in this case is whether LNPs in batches of Moderna's vaccine embody the lipid ratios covered by Plaintiffs' patents.[2] Each batch contains trillions of LNPs, each of which can have a different lipid ratio. Unlike cases involving products like an iPhone, where each product of the same model is essentially identical, discovery to date has revealed batch-to-batch variation in the lipid ratios of Moderna's vaccine. Moderna's own documents show that [redacted], which affects the infringement inquiry. *See, e.g.*, Ex. 1 (showing [redacted]); Ex. 2 at *146, *184 (showing [redacted]). And that [redacted]

Moderna has no reasonable basis to dispute the salience of samples from each batch of its vaccine, and any contrary argument contravenes the case law.[3] The only case Moderna has cited

[1] The parties also dispute discovery concerning batches manufactured overseas, which Plaintiffs allege were sold or offered for sale (and thereby infringed) in the U.S. Plaintiffs are filing a separate motion on this dispute, but for clarity, seek samples from all Moderna's batches, including those manufactured overseas. Moderna to date has only identified U.S.-manufactured batches.
[2] While Moderna contends that the "particle[s]" in Plaintiffs' claims must be "finished" in the narrow sense of not being subject to further processing, this and other claim construction disputes, D.I. 129, do not affect this dispute on the particles in undisputedly *finished* drug product samples.
[3] *Everlight Elecs. Co. v. Nichia Corp.*, 2013 WL 6713789 at *2 (E.D. Mich. Dec. 20, 2013) (compelling production of "more than 1,000 Accused LED Products"); *Invensas Corp. v. Renesas*

on this issue involves a simple product ("test cups" for urine screening) without batch-to-batch variation. *Rembrandt Diagnostics, LP v. Innovocon, Inc.*, 2017 WL 4391707 (S.D. Cal. Oct. 3, 2017). Given Moderna's own data reflecting variation between batches, it is beyond cavil that samples of *each batch* matter in this case. Indeed, despite repeatedly refusing and delaying even to identify infringing batches and then offering only a handful, Ex. 3 at 1, Moderna abruptly reversed course and made an exploding offer of approximately 480 expired batches, which Plaintiffs accepted. Ex. 4 at 4, 7–9. As to the remaining batches, however, Moderna has agreed only to produce a single batch from each version or "part number" of its vaccine—roughly a dozen batches. Moderna's proposal is prejudicial, and the justifications it has offered, related to its own testing and burden, are dubious and do not justify depriving Plaintiffs of this critical discovery.

Moderna's proposal to produce a sample from a single batch per part number—when part numbers can comprise *hundreds* of batches—prejudices Plaintiffs substantially, and ignores the undisputed variability in lipid ratios across batches. This prejudice is acute because *Moderna* intends to select unilaterally the single batch. *See* Ex. 5 at 1. Nor does Moderna's proposal permit Plaintiffs to test both expired and unexpired batches, which is critical because Moderna (despite producing only expired batches) intends to dispute test results on the basis of expiry.

The fundamental problem with Moderna's proposal is that Moderna maintains its right to argue that *unproduced* batches do not infringe. Moderna cannot decline to produce batches only later to dispute infringement of what it withheld, thereby "den[ying Plaintiffs] the opportunity to conduct discovery." *Prism Techs., LLC v. T-Mobile USA Inc.*, 2015 WL 5883764, at *3 (D. Neb. Oct. 8, 2015). While Plaintiffs are amenable to Moderna limiting its sample production (albeit to more than one sample per part number, not unilaterally selected by Moderna), any such agreement "would have to include a stipulation [by Moderna] to not raise future objections" with respect to batches that have been withheld. *Wonderland Nurserygoods Co. v. Baby Trend, Inc.*, 2021 WL 2315191, at *4 (C.D. Cal. June 7, 2021); *Apple Inc. v. Samsung Elecs. Co.*, 2012 WL 1511901, at *6 (N.D. Cal. Jan. 27, 2012) ("[T]o reduce Samsung's burden . . . Samsung can negotiate a stipulation that its production adequately represents . . . the entire set of accused products."). While Plaintiffs bear the burden of proving infringement, the choice for Moderna is simple: produce samples from each batch or agree not to dispute infringement of unproduced batches.

Moderna has argued that Plaintiffs do not need samples of every batch because Moderna has conducted its own testing. But it is a basic principle of discovery that Plaintiffs need not accept Moderna's testing as a substitute for their own. *Vitamins Online, Inc. v. Heartwise, Inc.*, 2016 WL 1305144, at *1–2 (D. Utah Mar. 31, 2016) (compelling production of lots despite defendant's claim that it "already . . . tested" "a majority of those lots"); *Seer Sys., Inc. v. Beatnik, Inc.*, 2006 WL 1180058 at *1–2 (N.D. Cal. May 3, 2006) (ordering samples *in addition* to technical documents). Moderna may tout its production of "400,000 pages" of regulatory submissions, but those documents largely comprise information irrelevant to infringement and are no substitute for the highly relevant samples of the accused product itself. Indeed, in all of the cases cited above,

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*Elecs. Corp.*, 2013 WL 1776112, at *1 (D. Del. Apr. 24, 2013); *P&G Co. v. Be Well Mktg., Inc.*, 2013 WL 152801, at *5–6 (M.D. Pa. Jan. 15, 2013); *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, 2016 WL 675553, at *1 (D. Del. Feb. 12, 2016); *3Com Corp. v. D-Link Sys., Inc.*, 2007 WL 949596, at *1–2 (N.D. Cal. Mar. 27, 2007) (ordering production of code for "all" accused products and "all missing versions"); *Alloc, Inc. v. Unilin Beheer B.V.*, 2006 WL 757871, at *4 (E.D. Wis. Mar. 24, 2006) (rejecting production only of products made after a certain date).

substantial document discovery did not obviate the need for sufficient samples. In any event, Moderna's own testing need not be accepted uncritically—particularly given that Moderna conducted it while attacking the asserted patents unsuccessfully before the PTAB and Federal Circuit—and where the testing [redacted]. *E.g.*, D.I. 1-1, 91. While the former might be relevant to the latter, they are not the same.

Moderna also has argued that the production of samples is burdensome. Any burden is proportional to the hundreds of millions of infringing doses it has sold (each batch contains tens of thousands of doses). There is no dispute that samples from each batch are readily available and accessible as part of Moderna's FDA "regulatory retain." Ex. 6 at 3; *Vitamins Online*, 2016 WL 1305144, at *2 (compelling samples from retain). This "regulatory retain" necessarily permits Moderna to furnish, expeditiously, any batch(es) FDA requests. It is not burdensome for Moderna to produce samples of its batches; it simply does not want to produce them *to Plaintiffs*. Indeed, contrary to any notion of burden here, Moderna shifted, on a dime, from arguing for months that producing more than 13 batches was "extremely burdensome" to demanding that Plaintiffs accept 480 batches within 3 business days. Ex. 4 at 1. Moderna is able to produce samples when it so chooses. Regardless, Moderna's purported burden cannot outweigh the prejudice from its single-batch-per-part-number proposal. While Plaintiffs have sought, for months, a compromise that limits Moderna's burden without prejudicing Plaintiffs, any compromise in which Moderna produces samples from fewer than all batches is undermined by Moderna's unqualified reservation to dispute infringement as to unproduced batches. Moderna cannot simultaneously deny Plaintiffs discovery while reserving its ability to dispute infringement of what it has withheld.

[redacted] **and Raw Data (RFP Nos. 108, 174).** In its process for making the accused vaccine, Moderna [redacted] Ex. 7 at *837. Moderna objects that [redacted] and therefore does not infringe. Plaintiffs therefore requested samples of the particles in Moderna's process [redacted], but Moderna responded that these particles are impossible to collect. The ratio in this unavailable intermediate particle differs from the final drug product and can separately infringe the asserted claims to "particle[s]." Ex. 8 at *169–70. As such, Plaintiffs requested samples of [redacted], from which infringement of the unavailable intermediate can be determined. Ex. 5 at 3. Moderna refused to produce samples, as well as raw data from its lipid testing of [redacted].

The requested samples and data are relevant to infringement. [redacted], but Moderna uses [redacted]. The lipid ratios of [redacted]—which Plaintiffs seek to ascertain by testing samples and obtaining Moderna's data—are relevant to the lipid composition of potentially infringing particles [redacted]. Moreover, Moderna's documents reflect that [redacted] Ex. 8 at *167. Moderna's use of [redacted] in its "manufacturing processes [thus] bear[s] upon the properties of its finished products," entitling Plaintiffs to discovery. *Medtronic Ave, Inc. v. Adv. Cardio. Sys.*, 2004 WL 115594, at *3 (D. Del. Jan. 13, 2004). Sample production can be conducted according to the principles above; and the raw data underlying Moderna's testing in light of its stated intent to rely on its own test results is plainly relevant.

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