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**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

LETTER TO THE HONORABLE MITCHELL S. GOLDBERG IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL RULE 30(b)(6) TESTIMONY

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Dear Judge Goldberg:

For weeks, the parties have negotiated the scope of testimony to be provided in response to their respective Rule 30(b)(6) notices. Moderna ultimately agreed to provide testimony in response to 72 of Plaintiffs' 87 topics. Relevant to this motion, Moderna negotiated with Plaintiffs to reach a reasonable compromise on Plaintiffs' Topic Nos. 32 and 50, which Moderna consistently objected to on the grounds of relevance and burden. Plaintiffs squarely rejected all compromise efforts and moved to compel testimony on these topics. D.I. 287. Moderna opposes Plaintiffs' motion to compel and respectfully requests the Court deny it.

Topic No. 32

Plaintiffs' Topic No. 32 broadly seeks testimony on seven scientific articles—only one of which relates to Moderna's COVID-19 vaccine, the Accused Product in this case. The remainder relate to unaccused pipeline products, including vaccines for Zika virus and various influenza viruses and therapies for oncology, inherited genetic disorders, hemophilia, and diabetes. *See* D.I. 287, Exs. 3–8. Moderna objected to Topic No. 32 on the grounds of, *inter alia*, relevance and burden, and offered to prepare a witness to testify to the single article relating to the Accused Product. Plaintiffs rejected this compromise.

Topic No. 32 is Plaintiffs' latest effort to obtain expansive discovery into Moderna's unaccused pipeline products under the spurious rationale that they are part of the same vaccine platform and thus relevant to copying and willfulness. *See, e.g.*, D.I. 287 at 1. Plaintiffs raised almost the same argument when they moved to compel production of Moderna's Investigational New Drug (IND) applications for unaccused pipeline products. D.I. 184 at 1–2. In ruling on Plaintiffs' motion, the Court limited this discovery to the Chemistry, Manufacturing, and Controls sections of three INDs with similar molar ratios to the Accused Product. D.I. 229 at 2. Moderna has already agreed to prepare a witness on the selection of the lipid molar ratios used in the product candidates covered by those three INDs (Nos. 029026, 029493, and 029703) in response to Topic Nos. 29 and 30. Ex. 14. Plaintiffs should not be able to use a 30(b)(6) topic to sidestep the Court's order limiting discovery on unaccused products.

Plaintiffs' additional explanations of the purported relevance of Topic No. 32 are similarly unavailing. Although Plaintiffs assert that this topic is necessary to test Moderna's "ability to formulate mRNA-LNPs using Plaintiffs' technology" and "Moderna's purported development of its own LNP technology," D.I. 287 at 1, Moderna already agreed to provide a witness on development of its SM-102 LNP platform and the lipid molar ratios used in the Accused Product in response to Topic Nos. 23–28. Ex. 14. Plaintiffs have not explained what relevant information they hope to obtain that is not already covered by Topic Nos. 23–28 and the article identified in Topic No. 32, on which Moderna has agreed to provide a witness. Plaintiffs appear to suggest testimony on the remaining articles provides needed discovery into Moderna's methods of manufacture. While any such testimony is of, at best, questionable relevance to the Asserted Claims—which claim compositions, not methods of manufacture—Moderna has agreed to prepare a witness on Moderna's manufacturing methods in response to Topic Nos. 20–22. Ex. 14.

In the face of these unconvincing assertions of relevance, Plaintiffs suggest that there would be minimal burden on Moderna to investigate, for each article, "(a) the lipid molar ratio

used and the reason it was selected, (b) the identity of the lipids used, (c) the manufacturing method used to prepare the LNPs, (d) the tolerability and immunogenicity of the mRNA-LNPs featured in the study, and (e) the role that each study played in contributing to Moderna's development of its SM-102 LNP platform." D.I. 287 at 1. But that is not the case. The articles identified by Plaintiffs in Topic No. 32 were published years ago—more than a decade ago in the case of one article and at least five years ago in the case of five other articles. It would be extremely difficult, if not impossible, for Moderna to investigate the data, formulations, manufacturing methods, and other material underlying the information reported in each article, and the articles otherwise speak for themselves.

By way of example, the "proof of concept" article identified in Topic No. 32 was published in 2013, and the sole author, Antonin de Fougerolles, left Moderna that same year. The de Fougerolles article does not list LNP formulations, manufacturing methods used to prepare LNPs, and other categories of information identified by Plaintiffs in their motion as purportedly "minimally burdensome" for Moderna to investigate. The other six articles implicated by this topic are also missing this or similar information, and Moderna would need to locate and sift through years of information to prepare a witness on Plaintiffs' proposed topic scope. Plaintiffs' request that Moderna undertake burdensome investigations into unaccused products simply to provide testimony on Topic No. 32 is not proportional, particularly where Plaintiffs have failed to adequately articulate the relevance of the testimony sought. The parties are presently trying to schedule 25+ depositions in five weeks before fact discovery closes, and Moderna would be significantly prejudiced if it had to divert resources to conduct a burdensome and disproportionate investigation into various unaccused products.

Topic No. 50

Plaintiffs' position as to Topic No. 50 is similarly meritless. As explained below, Moderna has agreed to prepare various witnesses on topics related to Moderna's reliance on the § 1498 defense based on the U.S. Government's inclusion of the 52-227 clause in its C-0100 supply contract. D.I. 58. However, Plaintiffs insist on seeking a Moderna witness to testify to the ***Government's decision—not*** Moderna's—to affirm its authorization and consent for any patent liability by filing a Statement of Interest in this lawsuit in 2023 (D.I. 49). That is irrelevant to the § 1498 inquiry.

Moderna has already agreed to provide testimony on the only relevant aspect of Topic No. 50: the -0100 and -0017 Contracts, including the negotiation relating to the inclusion of FAR Clause 52.227-1 and /or FAR Clause 52.227-1 Alt I and an overview of the goods and services Moderna provided under that contract.[1] However, Plaintiffs have also raised baseless conspiracy theories that Moderna made a quid pro quo agreement with the Government by offering something in return for the Statement of Interest, such as discounted vaccines for the uninsured. *See* D.I. 59. Although this theory is unfounded (as confirmed by two years of discovery), Moderna offered a witness to confirm that Moderna had not "asked for, or offered or gave anything in exchange for, the Government's Statement of Interest" and "Moderna's decision to provide free vaccines for the

[1] Moderna has also agreed to provide testimony on other aspects of the -0100 and -0017 Contracts in response to Topic Nos. 45–48. Ex. 14.

uninsured as part of its Commitment to Patient Access in the U.S."[2] Ex. 14. Plaintiffs were still unsatisfied and filed this motion to compel. The parties' dispute boils down to whether it is relevant and proportional for Moderna to also provide a witness on Moderna's knowledge of the "***Government's decision*** to assert that Section 1498 applied to the -0010 contract and to file a statement of interest." D.I. 287, Ex. 10 at 4. It is not.

Moderna's knowledge of the Government's decision to file a Statement of Interest has no bearing on any issue in dispute or the application of § 1498. Throughout the meet-and-confer process, Plaintiffs continually failed to explain the relevance of this information, and their vague assertions of relevance in this motion provide no further clarity. For example, Plaintiffs suggest they need testimony on this additional scope in order to probe the "evidentiary value" of the Government's Statement of Interest. D.I. 287 at 2. But any concerns about "evidentiary value" should be resolved by Moderna's agreement to provide a witness to testify to "whether Moderna asked for, or offered or gave anything in exchange for, the Government's Statement of Interest." Ex. 14 at Topic No. 50. And as Moderna told Plaintiffs when the parties were negotiating the scope of Topic No. 50, any information regarding why the U.S. Government filed its Statement of Interest should be sought from the U.S. Government, which is the best-placed entity to answer these questions. Asking Moderna to speculate on decisions made by another entity is not a proper subject for Rule 30(b)(6) testimony.

Additionally, any suggestion by Plaintiffs that they need testimony on the full scope of Topic No. 50 to probe Moderna's communications with the U.S. Government and "dispute" Moderna's common interest privilege claims is unfounded. Moderna has produced thousands of communications with the U.S. Government in this case and withheld only ***five*** communications under the common interest privilege. By contrast, Plaintiffs have withheld ***over 6,000*** communications under the common interest privilege. That Plaintiffs identified "testing" Moderna's privilege claims as a rationale supporting their motion to compel demonstrates that they are interested in seeking discovery on discovery rather than testimony on relevant issues.

* * *

For the foregoing reasons, Moderna respectfully requests the Court deny Plaintiffs' motion to compel.

Respectfully,

/s/ Travis Murray

Travis Murray (#6882)

cc: All Counsel of Record (via CM/ECF and electronic mail)

[2] Plaintiffs assert in their motion that "Moderna has only agreed to offer testimony about negotiations concerning the referenced FAR provisions and 'whether Moderna asked for, or offered or gave anything in exchange for the Government's Statement of Interest.'" D.I. 287 at 2. That is incorrect, as Moderna also offered testimony on its decision to provide free vaccines for the uninsured. *See* Ex. 14 at Topic No. 50.

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