PUBLIC VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIONTECH SE and PFIZER INC.,
Petitioner

v.

MODERNATX, INC.
Patent Owner

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IPR2023-01359
Patent No. 10,933,127

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**PETITIONER'S PRELIMINARY STATEMENT REGARDING PATENT OWNER'S INCONSISTENT POSITIONS**

Prior to this IPR, when seeking FDA approval for commercialization of its COVID-19 mRNA vaccine, as well as previous mRNA vaccine candidates, Moderna candidly represented to the FDA that prior studies for ***related*** vaccines (*e.g.*, DNA vaccines, self-replicating mRNA vaccines) supported an expectation of safety and efficacy. But now, faced with invalidating vaccine prior art (*e.g.*, Schrum, which unequivocally discloses an mRNA vaccine formulated in a lipid nanoparticle, just as claimed), Moderna wrongly casts the same vaccine prior art as irrelevant.

For example, Moderna told the FDA that its mRNA-based vaccine candidates merely followed the [redacted] provided by [redacted]—it did so to benefit from that earlier safety and efficacy data. (Ex. 2060, 1-2 (emphasis added).) But in this IPR, Moderna now argues that there was "deep skepticism" about combining mRNA and LNP technology. (POPR, 13.) The Board should not allow Moderna to opportunistically embrace prior art before the FDA but now distance itself from the same prior art here. *See, e.g.*, 87 Fed. Reg. 45764 (July 29, 2022). The statements Moderna made to the FDA about this prior art support institution—at a minimum, the Board should institute to resolve the factual questions these inconsistencies raise.

## I. Moderna Statements Regarding Geall

The Petition presents Geall for its teaching of a SARS-CoV spike polypeptide (*i.e.*, a BetaCov S protein, as claimed) because Schrum—the primary reference—

incorporates Geall for the identity of the immunogen encoded by its mRNA vaccine. (Pet., 22, 38-39.) In an attempt to distinguish Geall's disclosure, Moderna argues that Geall's vaccine examples concern "saRNA," which is allegedly "materially different" from mRNA. (POPR, 38, 52-54; Moderna Preliminary Statement (Paper 10) ("MPS"), 1-2.) Moderna's argument is a red herring because Geall doesn't limit its disclosure to saRNA. (*See* Ex. 1010.) Moreover, Moderna's statement that Dr. Geall's work "discusses saRNA—not mRNA—vaccines"—suggesting that the Board can set aside Geall's teachings—is inconsistent with Moderna's statements to the FDA that this same work *did* involve ***mRNA*** vaccines. (*See* Ex. 2060 (statement #2, citing Exs. 2050, 2051, 2052) [redacted]. [1]) Moderna's FDA statements are also consistent with Schrum's disclosure that Geall is pertinent to mRNA vaccines.

Unable to explain its litigation-driven one-eighty, Moderna repeats an incantation that the statements to the FDA are "post-priority" (*see* MPS, 1-3); but this does not properly reconcile the inconsistencies. In fact, post-priority evidence can explain, *inter alia*, "how [the POSA] would have understood a prior art disclosure." *Dominion Dealer Sols., LLC v. AutoAlert, Inc*., IPR2014-00684, Paper 9 at 8 (Oct. 6, 2014); *see also* 87 Fed. Reg. 45764 (requiring disclosure of

[1] Statement # [ ] refers to the statements in Exhibit 2060 numbered by row.

inconsistent statements to PTO and FDA regardless of timing). And because the FDA submission about the prior art was outside the context of a disputed proceeding, it necessarily has a stronger hallmark of truth. *Cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005). If Moderna asserts that its POPR arguments are merely expressing the viewpoint of a POSA in 2015, whereas the FDA submissions are "post-priority" and do not reflect the perspective of a POSA in 2015, that argument also fails—after all, Moderna did not submit any expert testimony with its POPR on a POSA's understanding in 2015.

Moderna also contends for the first time that the challenged claims disclaim "saRNA" from the breadth of "mRNA." (MPS, 2-3.) Even if the Board were inclined to entertain a belated claim construction argument that "mRNA" as used in the claims excludes saRNA—when Moderna argued no such thing in its POPR (*see* POPR 4; Ex. 1035)—that is no impediment to institution because Moderna does not (and cannot) show that Geall is limited to saRNA. (*See* Ex. 1010.) Indeed, Moderna's reliance on Dr. Geall's work in its FDA submissions as providing proof of concept for "mRNA" vaccines and Schrum's incorporation of Geall in its mRNA vaccine section confirm that Dr. Geall's work is relevant to mRNA vaccines and that the claims are unpatentable under Moderna's belated claim construction.

## II. Moderna Statements Regarding DNA Vaccines

The Petition relies on Yang's teaching of the SARS-CoV spike protein as a

target antigen for a nucleic acid (DNA) vaccine: (1) as supporting motivation for that same antigen to be a target of an mRNA vaccine (Pet., 41-42), and (2) as an express teaching of a SARS-CoV spike protein as an encoded immunogen (Pet., 50-52.) In response, with no expert support, Moderna argues that DNA is so different from mRNA that a POSA would discard all prior art teachings about DNA vaccines as irrelevant. (POPR, 54-55, 57; Ex. 2060 (statement #4).) But to the FDA, Moderna emphasized that prior ***DNA*** vaccine studies allowed it to "anticipate[] that mRNA-1273 [Moderna's COVID-19 vaccine candidate] will generate robust immune responses to the 2019-n-CoV S protein." (Ex. 2060 (statement #4) (citing Ex. 2056, 6); *see also id.* (citing Exs. 2053-2055).[2]) And submissions in support of Moderna's mRNA vaccine clinical trials drew support from ***DNA*** vaccine studies conducted in 2004 and 2005. (Ex. 2060 (statement #4) (citing Exs. 2054, 2055).) Moderna cannot now argue that antigen targets of a DNA vaccine are irrelevant to an mRNA vaccine when it told the FDA the opposite based on a similar 2004 vaccine study.

## III. Moderna Statements Regarding Expectation of Success and Skepticism

In its POPR, Moderna argues that, at the time of the alleged invention,

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[2] Moderna does not (and cannot) deny its involvement in the authoring of Exhibits 2053-55, which are submissions to the FDA in support of clinical trials for mRNA-1273, Moderna's COVID-19 vaccine candidate. (*See* MPS, 3 n.1.)

combining mRNA and LNP technology for a vaccine was unprecedented (Ex. 2060 (statement #1)), the efficacy of mRNA vaccines was questionable (*id*., statement #3), and there were reasons not to pursue a coronavirus spike protein as a vaccine antigen (*id*., statements #5, #6). But these allegations are belied by Moderna's own statements to the FDA, or those that it knew were being submitted to the FDA, in support of conducting clinical trials for its COVID-19 vaccine candidate: LNP-mRNA combinations for a vaccine had already been successfully demonstrated by 2012 (*see* Ex. 2049); safety and efficacy of mRNA vaccines had been demonstrated by 2012 (*see* Exs. 2050, 2051, 2052); and vaccines encoding the SARS protein (a coronavirus spike protein) had been found to be "immunogenic," "safe," and "well tolerated" by 2004 (Exs. 2054, 2055; *see also* Ex. 2057).

Moderna seeks to explain away these inconsistencies by contending that the POPR "accurately quote[d]" Du. (MPS, 5.) But Moderna did not just quote Du; it alleged that there was "***widespread skepticism*** regarding pursuit of a coronavirus spike protein as a vaccine antigen" (POPR, 55-56 (emphasis added)) while withholding from the Board prior studies ***known*** to Moderna (*e.g.*, Kam 2007 cited in Ex. 2057) demonstrating the absence of the purported "widespread" skepticism (*see* Ex. 2060 (statements #5, #6).

The Board should institute trial to resolve the factual disputes concerning Moderna's inconsistent positions.

Respectfully submitted,

Dated: January 23, 2024

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## CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2024, I caused a true and correct copy of the foregoing Petitioner's Preliminary Statement Regarding Patent Owner's Inconsistent Positions to be served by email at the following email addresses of record:

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