UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioners,

v.

MODERNA TX, INC.,
Patent Owner.

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Case IPR2023-01359
Patent No. 10,933,127

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**PATENT OWNER'S OBJECTIONS TO PETITIONER'S ORAL HEARING DEMONSTRATIVES**

Pursuant to the Board's November 12, 2024 Order Setting Oral Argument (Paper 76), Patent Owner, Moderna Tx, Inc., and Petitioners, BioNTech SE and Pfizer Inc., met and conferred regarding objections to the oral hearing demonstratives on December 2, 2024. Patent Owner hereby submits the following objections to Petitioners' demonstrative slides.

1. Slide 15: Patent Owner objects to Petitioners' presentation of "Schrum's Claims Compared to the Challenged Claims," including claims 11 and 12, which Petitioners never previously cited in their Papers, as improper new argument not discussed in Petitioners' Papers.

2. Slide 50: Patent Owner objects to Petitioners' assertion that "Patent Owner's other attempt at injecting an additional claim limitation fails" as improper new argument to Patent Owner's Sur-Reply that is outside of the trial record and inconsistent with the claim construction petitioners advanced in the petition.

3. Slide 54: Patent Owner objects to Petitioners' assertion that "Schrum's immunogen-encoding mRNA vaccines are an 'mmRNA of the invention' delivered using lipid nanoparticles" as improper new argument not discussed in Petitioners' Papers.

4. Slide 55: Patent Owner objects to Petitioners' use of Moon Reply Decl. (Ex. 1161) at ¶35, which was not specifically discussed in Petitioners'

Papers, as improper use of expert testimony for improper new argument to Patent Owner's Sur-Reply that is outside of the trial record.

5. Slide 56: Patent Owner objects to Petitioners' assertion that "POSA would have understood that 'modified RNA' refers to modified mRNA based on Schrum," citing Moon Reply Decl. (Ex. 1161) at ¶41, which was not specifically discussed in Petitioners' Papers, as improper use of expert testimony for improper new argument not discussed in Petitioners' Papers.

6. Slide 76: Patent Owner objects to Petitioners' assertion that "*[e]very* SARS-CoV S protein vaccine of record induced an immune response," citing Griffin Reply Decl. (Ex. 1159) at ¶197, as improper new argument relying on expert testimony not discussed in Petitioners' Papers.

7. Slide 77: Patent Owner objects to Petitioners' support of the assertion that "A POSA Would Have Reasonably Expected to Induce an Immune Response and Neutralizing Antibodies" with Buchholz (Ex. 1132) at 9809 and Du (Ex. 1031) at 229, which were never cited by Petitioners to support that assertion, as improper new argument not discussed in Petitioners' Papers.

8. Slide 78: Patent Owner objects to Petitioners' support of the assertion that "A POSA Would Have Reasonably Expected to Induce an Immune Response and Neutralizing Antibodies" with Wang (Ex. 1101) at 2 and Yang (Ex. 1011) at

561, which were never cited by Petitioners to support that assertion, as improper new argument not discussed in Petitioners' Papers.

9. Slide 87: Patent Owner objects to Petitioners' assertions that there is "[n]o evidence of any failure to achieve challenged claims" and "[n]o evidence of *any* betacoronavirus S protein-based vaccine that failed to induce an immune response," citing Fuller Dep. (Ex. 1104) at 65:15-66:2, as improper new argument relying on expert testimony not discussed in Petitioners' Papers.

10. Slide 89: Patent Owner objects to Petitioners' assertion that "Patent Owner has not cited a *single* S protein vaccine that failed to induce an immune response," citing Fuller Dep. (Ex. 1104) at 41:20-42:3, as improper new argument relying on expert testimony not discussed in Petitioners' Papers.

11. Slide 90: Patent Owner objects to Petitioners' assertion that there is "No Relevant Failure in the Prior Art," including citation to Ex. 2046 and Ex. 1119, which Petitioners never cited in their Papers, as improper new argument not discussed in Petitioners' Papers.

12. Slide 99: Patent Owner objects to Petitioners' improper new argument, not made in its Papers, that "Vennema (Ex. 2029) does not show disease enhancement by betacoronavirus vaccines" and "Patent Owner's principal evidence of enhanced disease is Vennema 1990 (Ex. 2029), which studied feline

infectious peritonitis ("FIP") virus – *not* a betacoronavirus," including Petitioners' citation to Vennema (Ex. 2029), Yang (Ex. 1011) ("The feline infectious peritonitis virus is a coronavirus that causes … possible immune potentiation of the disease and by viral evolution.") at 563, and Bucholz (Ex. 1132) at 9809, which were not cited in Petitioners' Papers to support Petitioners' new argument.

13. Slide 100: Patent Owner objects to Petitioners' citation of Jaume (Ex. 2030) and assertions that "Jaume (Ex. 2030) would not have dissuaded a POSA from using S-protein" and "Jaume Reported that 'No Evidence of Productive Virus Replication and Spread,'" as improper new argument because Petitioners never cited Jaume in their Papers.

14. Slide 101: Patent Owner objects to Petitioners' assertion that "Jaume's (Ex. 2030) antibody administration would not have dissuaded a POSA from using S-protein," relying on Krause Decl. (Ex. 2200) at ¶161, which Petitioners never cited in their Papers, and Griffin Reply Decl. (Ex. 1159) at ¶¶218-219 as improper new argument relying on expert testimony not discussed in Petitioners' Papers.

15. Slide 102: Patent Owner objects to Petitioners' assertion that "Dr. Fuller's testimony further confirms that ADE would not have dissuaded a POSA from pursuing a mRNA vaccine encoding the S-protein," citing Fuller Dep. (Ex.

1159) at ¶214 and Petsch (Ex. 2025) at Figure 1e (characterized by Petitioners with the statement "IFN-γ is a cytokine that is primarily produced by Th1 cells"), which Petitioners' never cited in their Papers, as improper new argument to Patent Owner's Sur-Reply that is outside of the trial record.

16. Slide 103: Patent Owner objects to Petitioners' assertion that "The S-Protein was the 'clear molecule with which [the virus] enters lung cells' that was a 'wanted poster' for the immune system," citing previously uncited portions of Ex. 2106 at 69 ("Unlike many other viruses…scrutinize and learn to attack"), as improper new argument not discussed in Petitioners' Papers.

17. Slide 104: Patent Owner objects to Petitioners' assertion that "Yang 2005 found ADE in a civet virus, but emphasizes that no ADE has ever been observed in human SARS-CoV" as improper new argument not discussed in Petitioners' Papers.

18. Slide 108: Patent Owner objects to Petitioners' use of Schrum (Ex. 1009) at ¶998 to support Petitioners' assertion that "A POSA Had Good Reason to Use Lipid Nanoparticle Formulations" as improper new reasonable expectation of success and motivation to combine argument not discussed in Petitioners' Papers.

19. Slide 109: Patent Owner objects to Petitioners' use of Ex. 2021 at 14604 to support the assertion that "By 2015, prior art had already demonstrated

that use of lipid nanoparticles to deliver immunogen-encoding **mRNA** 'substantially increased' vaccine performance" (emphasis added) as improper new argument not discussed in Petitioners' Papers.

20. Slide 110: Patent Owner objects to Petitioners' use of Schrum (Ex. 1009) at ¶¶397, 998 to support Petitioners' assertion that "A POSA Had Good Reason to Use Lipid Nanoparticle Formulations" and Petitioners' use of Fuller Dep. (Ex. 1104), 50:21-51:2, which Petitioners never cited in their Papers to support this assertion, as improper new reasonable expectation of success and motivation to combine argument not discussed in Petitioners' Papers.

21. Slide 111: Patent Owner objects to Petitioners' use of Fuller Dep. (Ex. 1104), 192:4-11, which Petitioners never cited in their Papers, to support Petitioners' assertions ("A POSA Had Good Reason to Use Lipid Nanoparticle Formulations"; "Dr. Fuller confirmed that the benefits described in Ex. 2021 were equally applicable to non-replicating mRNA") as improper use of expert testimony to support new arguments not discussed in Petitioners' Papers.

22. Slide 116: Patent Owner objects to Petitioners' use of Ex. 1099, which Petitioners never cited in their Papers, to support Petitioners' assertion that "The Record Confirms a POSA Would Have Considered Data from Other Vaccine Modalities" as an improper new argument not discussed in Petitioners' Papers.

23. Slide 120: Patent Owner objects to Petitioners' use of Griffin Reply Decl. (Ex. 1159) at ¶256 to support the assertion that "obviousness does not require identical immune response levels" as improper new argument not discussed in Petitioners' Papers and improper reliance on expert testimony to support the new argument.

24. Slide 121: Patent Owner objects to Petitioners' assertion that "[c]ontrary to Dr. Fuller's Testimony, the record demonstrates that non-amplifying mRNA can generate an immune response," citing Fuller Decl. (Ex. 2199) at ¶557 and Brito (Ex. 2005) at 2124, which Petitioners never cited in their Papers, as improper new argument to Patent Owner's Sur-Reply that is outside of the trial record and improper reliance on expert testimony to support the new argument.

25. Slide 122: Patent Owner objects to Petitioners' assertions that "Dr. Fuller's opinion based on her recollections are inaccurate and do not reflect what a POSA would have known by 2015" and "Petsch 2012 demonstrates that mRNA vaccines induced an immune response at doses higher than in Brito," citing Fuller Decl. (Ex. 2199) at ¶557 and Petsch (Ex. 2025) at 1215, which Petitioners never cited in their Papers, as improper new argument to Patent Owner's Sur-Reply that is outside of the trial record.

26. Slide 126: Patent Owner objects to Petitioners' assertion that "data of record *exclusively* shows that S protein vaccines induce an immune response—Patent Owner has not adduced any evidence of an S protein vaccine *failing* to induce an immune response" as an improper new argument not discussed in Petitioners' Papers.

27. Slide 128: Patent Owner objects to Petitioners' assertions that "Alleged Secondary Considerations Evidence Is Not Reasonably Commensurate with the Scope of the Claims," including that "Claims cover: mRNA encoding for any betacoronavirus S protein; Any mRNA sequence encoding for such protein; Any lipid nanoparticle formulation; ('127) Any level of immune response in any mammal." as improperly newly arguing the reasonable commensurate standard, which was not discussed in Petitioners' Papers.

28. Slide 129: Patent Owner objects to Petitioners' assertions that "Alleged Secondary Considerations Evidence Is Not Reasonably Commensurate with the Scope of the Claims," including that there is "No evidence of: S protein for a betacoronavirus other than SARS-CoV-2; S protein subunit for any betacoronavirus; Vaccines without the 1-methylpseudouridine modification; Vaccines without the particular, optimized LNP formulations, mRNA sequences 5' caps, 5' and 3' untranslated regions, [and] codon optimizations used in

Comirnaty/Spikevax; Vaccines not developed in response to an unprecedented global pandemic" as improperly newly arguing the reasonable commensurate standard, which was not discussed in Petitioners' Papers.

29. Slide 135: Patent Owner objects to Petitioners' use of Chan Decl. (Ex. 2198) at ¶¶180-181, which Petitioners never cited in their Papers, as an improper use of expert testimony.

30. Slide 136: Patent Owner objects to Petitioners' use of Chan Decl. (Ex. 2198) at ¶182, which Petitioners never cited in their Papers, as an improper use of expert testimony.

31. Slide 137: Patent Owner objects to Petitioners' use of Chan Dep. (Ex. 1152) at 56:6-18 and Moon Reply Decl. (Ex. 1161) at ¶¶44-51, which Petitioners never cited in their Papers, as improper uses of expert testimony.

Respectfully Submitted,

/Emily R. Whelan/

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Dated: December 9, 2024

## CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2024, I caused a true and correct copy of the below documents:

- Patent Owner's Objections to Petitioner's Oral Hearing Demonstratives

to be served via e-mail, as consented to by Petitioner, to:

COVIDPatentPfizer@wc.com
BioNTech-Moderna-IPR@paulhastings.com

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